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Agri-Food Biotechnologies Regulation: a comparative perspective

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Abstract

Technological change impacts the agri-food sector and generates new competitive pressure. As well as the digital technologies that are introducing new business models and revolutionizing the traditional food chain, with new consumers' protection tools, emerging genetic engineering techniques (e.g. gene editing) - which the present article is focused on – are thoroughly impacting food nature and production modality. This new step of scientific progress is also blurring the line between issues traditionally ascribed to the different fields of environment law and safety law. Biotechnology is, in fact, one of the strategic keys enabling technologies to support a new green and sustainable economy (i.e. bioeconomy) responding to the need for new food production technology, more efficient resource use, and responsible value chains, in a context in which sustainable food system is promoted by the *European Green Deal* and the *Farm to Fork* strategies.

Analyzing the current European debate on the appropriateness of stringent GMO legislation to new DNA alterations (such as gene editing) and discussing upcoming changes, such as for instance the perspective of overcoming the "safe enough" narrative (EGE, 2021), and the proposal stemming from the EU Commission's Study on the status of new genomic techniques (April 29, 2021), the article aims at finding out how the European Union manages to balance economic interests with consumers' fundamental rights protection to maintain the appropriate functionality of the internal market fostering innovation. The comparative study between the two main regulatory models, historically characterizing different food cultures and

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contexts will be analyzed in parallel with a keen eye to the most recent debate about the EU need to empower new innovative technologies for sustainability will lead us to express some critical remarks toward the factors that prevent the development of an adequate regulatory environment for agri-food biotechnologies.

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Keywords

European Law – Regulatory models – Safety – Consumers protection – Environment – Health Protection – Biotechnologies.

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1. Introduction

The almost forty years long European debate about genetically modified organisms (from now on: GMO) authorization and suitable regulatory policy[1], is considered a pivotal experience to study the impact of scientific uncertainty on culture, policy and law. Furthermore, it represents the result of the swinging faith and skepticism in agri-food biotechnologies both in public perception and stakeholders' assessment.

Instead of coming to an end, the debate recently intensified and characterized the EU again: in the past few years, a innovative technique for genome editing, CRISPR-Cas, with wider potential and easier applicability, has rapidly advanced

[1] Between 1985 and 2010, the EU invested about € 250 million to assess the safety of GMOs. It also collected and made public the available data in two publications. The first one, the European legislation on GMOs, dates back to the 1990s (Council Directive (EC) on the deliberate release into the environment of genetically modified organisms, [1990] OJ L 117, pp. 15-27). The third whereas of this Directive stated that: "the protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release of genetically modified organisms (GMOs) into the environment: in reality, living organisms containing genes of different species, whether they are understood in the scientific sense (as organisms resulting from transgenesis), or in the legal sense introduced in the EC Directive No. 18/2001, have occupied the scene since the '70s. Legal, scientific and commonly understood by society do not coincide. For more information see: E. Sirsi, 'In tema di etichettatura dei prodotti geneticamente modificati', in F. Maggino et al. (eds), *I Georgofili. Atti della Accademia dei Georgofili* (Edizioni Polistampa, 2015); F. Albújar, Van der Meulen, 'The Legal GMO Concept Reassessment of the GMO definition in the light of new breeding techniques (NBTs)' (2017) *European Institute for Food Law Working Paper Series* 03. For a definition of GMO see ECJ case C-442/09, *Bablok* [2011] ECR I-7419, para 62. Opposing countries include Italy, Austria and Hungary, as well as numerous NGOs. In the European market there is an implicit "feeling" of aversion to GMOs linked to their presumed potential danger, although minimal traces, not exceeding 0.9%, are tolerated. This means that when the presence of GMOs in food products is accidental, or derives from contamination not otherwise avoidable, and does not exceed that threshold, the food will not be subject to the labelling requirements specifically provided for by Regulation n. 1830/2003 EC, by virtue of art. 12, paragraph 2, of the same. Food containing GMOs that exceeds this threshold, on the other hand, will have to meet the requirements of this regulation, which has a supplementary nature compared to reg. n. 1169/2011 EU. Consumers are concerned about the maintenance of biodiversity; the possible change in ecological balances; the limitations on the development of a competitive market; and the possible allergenicity or antibiotic resistance of food derived from or containing GMOs. States in favour, on the other hand, identify a means of improving plant species (e.g., increased resistance to insect virus pesticides), adaptability to climates, increased productivity in agriculture, reduced impact on the environment, and response to food security issues. R. Defez, *Il caso ogm. Il dibattito sugli organismi geneticamente modificati* (Carocci, 2016).

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plant biology research and the development of applications for plant breeding. As the paper will explain, the issue heated up in 2018 after the European Court of Justice (ECJ) ruled that organisms obtained by new plant breeding techniques (from now on: NBTs) should, in principle, fall under the GMO Directive.

The spread of the techniques for artificial modification of the genome through targeted alterations of DNA and RNA are competing with traditional phenotype use of living organisms. All in all, these new genetic engineering techniques not only are modifying existing organisms, but they can also create new cells and new organisms[2].

Regardless of the different point of view, it is undeniable that the use of agri-food biotechnologies affects a multiplicity of sectors and socio-economic interests[3] and fuels many doubts about unknown long-term effects of consuming biotech foods on humans, including nutritional differences and new diseases developed in the human gut and allergic reactions raise uncertainty. These fears, however, are not, in most cases, supported by scientific data[4].

The identification of the regulatory model for biotechnology becomes, therefore, a complex and multidimensional objective[5], such that any public decision implies choices of a discretionary nature[6]: this is because governance is a crucial issue and it is thus strategic to unfold its multiple facets both on environment and safety sides. A primary factor is the state of the existing and emerging legislative and regulatory strategies across the various purposes and domains (humans, non-human animals,

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[2] N. De Sadeleer, 'Marketing and Cultivation of GMOs in the EU. An Uncertain Balance between Centrifugal and Centripetal Forces', (2015) 6 *Eur. J. Risk Reg.* 532.

[3] For the same reason in 2006, the World Trade Organization (WTO) had condemned the EU to remove an alleged moratorium against GMOs from Canada, the United States and Argentina for lack of sufficient scientific information. EC - *Measures Affecting the Approval and Marketing of Products* (29 September 2006) WT/DS/291, 292, 293, *Reports of the Panel*, Geneva.

[4] D. Bressanini, B. Mautino, *Contro natura. Dagli OGM al «bio», falsi allarmi e verità nascoste del cibo che portiamo in tavola* (Rizzoli, 2016).

[5] See D. Bevilacqua, 'La regolazione pubblica degli OGM tra tecnica e precauzione', (2016) 2 *Riv. crit. dir. priv.* 275.

[6] See ibid [278]; F. Cittadino, 'Libera circolazione degli OGM: più spazio per la tutela dell'ambiente alla luce della direttiva (UE) 2015/412?', (2016) 1 *Riv. giur. amb.* 219.

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plants, microorganisms, gene drives); a pertinent component is the historical dimension and legacy of legislative approaches (with questions of path dependency, institutional mimesis, transnational epistemic communities, and learning forms), which also demand to be addressed there.

It is possible to trace several evolutionary steps in the agri-food biotechnology policy: at first the debate was focused on the opposing positions for and against GMOs; at a second time, the attention was aimed at investigating the real extent of scientific uncertainty about the effects of new agri-food products on human health and/or the environment when, to date, there is still scientific evidence about the actual danger of the use of genetic engineering in the agri-food field. Finally, the promotion of a holistic approach aimed at weighing also other non-measurable components, including ethical ones[7]. In practical terms, following the recent Ege Opinion n. 32[8], disputing the 'safe enough' narrative implies questioning the inclination of scientific and technological developments to shape governance and indeed ethics. This also extends to coordination matters, diversity, inequalities and power relations. As a matter of fact, 'safety' or 'trustworthiness' do not pertain merely to technologies yet also extend to institutions and forms of governance in societies – including matters of oversight as well as of democracy and rule of law.

In this perspective, comparative research has already presented findings to show to what extent public perceptions and food culture are crucial elements for determining the acceptance of a model of food governance in a domain where "technological risks"[9], unlike simple risks (e.g. car accidents), cannot be calculated according to traditional technocratic models, namely as a statistically foreseeable

[7] Among the many see G.E. Seralini, E. Clair, R. Mesnage, S. Gress, N. Defarge; M. Malatestab, D. Hennequin, J. Spiroux de Vendomois, 'Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize', (2012) 50(11) *Food and Chemical Toxicology* 4221.

[8] European Group on Ethics in Science and New Technologies Opinion on Ethics of Genome Editing, Opinion n. 32, March 2021, available at: https://ec.europa.eu/info/sites/default/files/research_and_innovation/ege/ege_ethics_of_genome_editing-opinion_publication.pdf.

[9] M. Weimer, L. Marin, 'The Role of Law in Managing the Tension between Risk and Innovation: Introduction to the Special Issue on Regulating New and Emerging Technologies' (2016) 7(3) *European Journal of Risk Regulation* 469.

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function of probability.[10] Within this thread the perspective implemented in this paper is inserted.

Consequently, to balance new techniques' implementation of global environmental sustainability with safety exigence, European Institutions are already involved in analyzing in depth how law and regulation can successfully adapt to biotech progress integrating both legal and non-legal tools[11].

This article starts from the analyzes of the different regulatory models and specific mechanisms applied in different geopolitical contexts to agri-food biotechnologies with attention to their legal culture. For this purpose, from a methodological point of view, the analysis aims to engage with real-world issues and takes a practical perspective, following the path of contemporary comparative legal scholarship[12]. Moreover, even if the examined subject impacts on two distinct fields

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[10] M. Graziadei, 'Modernisation and Risk Regulation in the Italian Food Sector', in M. Dyson M. (ed.), *Regulating Risk through Private law* (Intersentia, 2018) 347; M. Weimer, L. Marin, 'The Role of Law in Managing the Tension between Risk and Innovation: Introduction to the Special Issue on Regulating New and Emerging Technologies' (2016) 7(3) *European Journal of Risk Regulation* 469.

[11] As a matter of fact, for long time, questions concerning the socio-economic, ethical and wider ecological impacts on the technology-including have been excluded as bona fide questions within a strictly risk-based regulatory framework, see S. Jasanoff, 'Commentary: Between risk and precaution – reassessing the future of GM crops' (2000) 3(3) *Journal of Risk Research* 277. Attempts to address uncertainty by reducing the distance between understanding the true degree of risk (scientific fact) and adopting legal measures taken on the basis of assessments that are not strictly scientific can already be found in more recent legislation: for example, with the introduction of dir. no. 350/2018 EU (Commission Directive (EU) 350/2018 amending dir. No. 18/2001 EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms [2018] O.J L67/30), in the part relating to the environmental risk assessment of GMOs "in order to adapt to technical progress and to take into account the experience gained in the environmental risk assessment of genetically modified plants."

[12] U. Kischel, *Comparative Law* (Oxford University Press, 2019); M. Siems, 'New Directions in Comparative Law' in M. Reimann, R. Zimmermann (eds.), *The Oxford Handbook of Comparative Law* (Oxford University Press, 2nd edition, 2019); H. Spamann, 'Empirical Comparative Law' (2015) 11 *Annual Review of Law and Social Science* 131; D. Nelken, 'Comparative Legal Research and Legal Culture: Facts, Approaches, and Values' (2016) 12(1) *Annual Review of Law and Social Science* 45-62 ; A. Riles, 'Comparative Law and Socio-Legal Studies' in M. Reimann, R. Zimmermann, *The Oxford Handbook of Comparative Law* (Oxford University Press, II ed., 2019) 773.

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- environment law and consumers' protection law - the paper will individualize some issues in common share, and it prospects a more unified approach[13].

Findings will lead to express some critical remarks regarding, particularly, the European model. It will also focus on factors that prevent the development of an appropriate regulatory environment in this critical area.

Finally, the comparison will offer some food for thought toward the "suitable ingredients" of a successful regulatory model promoting biotech foods respectful of traditions and vice-versa. These will be some preliminary key attitudes for designing an effective and socially desirable biotech regulation, coherent to balance the EU innovation goal and cultural food policy.

The paper is articulated in three parts: it starts from the reconstruction of the landscape of agri-food biotechnologies (§ 2), shedding light on the variety and diversity of them in light of EU case law (§ 3); the second part is dedicated to the exploration of the main regulatory mechanisms, namely, precautionary principle and substantial equivalence principle underlying the different models (§§ 4-5); the third part, instead, analyzes the different regulations in force in different countries to reflect on the European model, included in the broader framework of objectives expressed by the EU Green Deal[14] and the Farm to Fork strategy[15]. This part will

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[13] This remark is in line with the path traced by recent literature: see P. Macnaghten, M.G.L. Habets, 'Breaking the impasse. Towards a forward-looking governance framework for gene-editing with plants' (2020) 2 *Plant People Planet* 353. The article offers a comprehensive view of perspectives and counter-perspectives on the environment and food security effects of technological manipulations.

[14] Commission Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on the European Green Deal [2019], (COM(2019) 640 final).

[15] Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system [2020] (COM/2020/381 final). In brief, the European Green Deal sets out how to make Europe the first climate-neutral continent by 2050. It maps a new, sustainable and inclusive growth strategy to boost the economy, improve people's health and quality of life, care for nature, and leave no one behind. The Farm to Fork Strategy is at the heart of the Green Deal. It addresses comprehensively the challenges of sustainable food systems and recognizes the inextricable links between healthy people, healthy societies and a healthy planet. The strategy is also central to the Commission's agenda to achieve the United Nations' Sustainable Development Goals (SDGs). All citizens and operators across value chains, in the EU

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identify contradictory aspects that prevent the predisposition of a coherent and adequate regulation (§§ 6-7). The final purpose will be to investigate which ones are implied in the European current model and would potentially constrain the development of an adequate regulatory regime, letting Europe in stand by position.

2. Law and the variety of innovative agri-food biotechnologies: a matter of classification

As a matter of fact, varietal improvement techniques are numerous and a «failure to distinguish between biotechnology and biotechnology has to often lead to the impoverishment of the debate»[16].

Although in the European regulatory framework it is necessary to navigate between positive and negative definitions of the various biotechnological techniques, traditionally an organism is deemed to be genetically modified where its genetic endowment is altered in a way that cannot be achieved naturally either by multiplication or recombination[17]. More precisely, the EU Directive 2001/18 defines a GMO as "*genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*" (art. 2 n. 2 of the Directive)[18].

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and elsewhere, should benefit from a just transition, especially in the aftermath of the COVID-19 pandemic and the economic downturn. A shift to a sustainable food system can bring environmental, health and social benefits, offer economic gains and ensure that the recovery from the crisis puts us onto a sustainable path.

[16] J. Kloppenburg, 'Impeding dispossession, enabling repression: biological open source and the recovery of seed sovereignty' (2010) 10(3) *Journal Agrarian Change* 381. It has to be noted that in 2017 the Scientific Advise Mechanism (SAM) published the explanatory note title "New Techniques in Agricultural Biotechnology", 2/2017, where it recognized the heterogeneity among NGTs and the fact that this was reflected in the variety of NGT products.

[17] See in particular Article 2(2) of the *Convention on Biological Diversity*; Article 5(5)(2) of the German Federal Law of 21 March 2003 on Non-Human Gene Technology; and Article L 531-1(2) of the French Environmental Code.

[18] When the pollen stemming from a variety of genetically modified corn loses its capacity of reproduction and is devoid of any capacity to transfer genetic material, it does not constitute a GMO within the meaning of secondary law anymore. See Case C-442/09 *Bablok* [2011] ECR I-7419, para. 62.

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Even though this definition is now known to all, it is useful to recall it in order to point out that itself and its extension have become crucial in relation to the evolution of technologies of genetic modification that has led, gradually, to introduce the differentiation between traditional or conventional biotechnology and new biotechnology.

To use the terminology recently adopted in the EGE's Opinion n. 32, the term conventional GMOs will be used to refer to plant GMOs obtained by recombinant DNA technology and characterized by the presence of introduced DNA sequences from the same or other species in the final organism.

We first identified the definition of GMO as it has become a new battleground with the advent of the *new breeding techniques*[19]. Genome editing is a group of new directed mutagenesis techniques that facilitate addition, removal, or alteration of DNA sequences at a specific location in the genome.

The identification of DNA alterations from genome editing that are not unique remains, therefore, extremely difficult, as the altered sequences may mimic naturally occurring sequence variants, or they may not be distinguishable from those alterations obtained with conventional mutagenesis.

Like all techniques, also those of mutagenesis have evolved over time: before the adoption of the GMO Directive (dir. n. 18/2001 CE) only traditional methods of mutagenesis applied *in vivo* on whole plants were used. With more recent progress, these techniques have also been used to obtain GMOs.

The main difficulty has been – and still with reference to NBTs – to outline the area of genetically modified organisms, for which Europe has deemed necessary an ad hoc regulation.

The origins of the concerns lies in the controversial nature of the object of the analysis: food or seeds resulting from the application of modern biotechnology. The long European debate on the safety of GMOs, which has occupied the scene since the 1970s, is a paradigmatic example of the way in which scientific information on

[19] On the subject, most recently E. Sirsi, *Note sulla definizione giuridica di OGM e sulle cd New Breeding Techniques*, report given at the Senate 9th Committee (Agriculture and Food Production) Hearing on 7/13/2016, available at: www.senato.it.

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safety filter – into the choices made by legislators to shape innovation: on many occasions, scientific uncertainty concerning the dynamics of GMO propagation in the environment, or impacting on allergenicity or biodiversity depletion has led, on the one hand, consumers to identify in the products of progress risks never attested by scientific data; and on the other hand, European legislators to make extensive use of precautionary logic. In the knowledge that not all stages of uncertainty lead to reification of risk, and not all legitimize recourse to the precautionary principle, a more integrated analysis of scientific and legal data could reveal that some products that lead to alarm are in fact not dangerous[20].

This appears to be a controversial point even with respect to proposals developed at the international level to standardize the concept of GMOs, biotechnology and new biotechnologies (art. 12 del *Codex alimentarius*; Cartagena Protocol, *etc*).

In the wide spectrum of the plurality of sources intervened to regulate GMO food[21], the circumstance that the techniques of genetic modification have been employed with reference to the most important *commodities* justifies, in fact, the interest also of the centers of standardization of international importance, and explain the debate that has surrounded the stipulation of some International Treaties[22]. The most significant normative context at the international level to evaluate the legitimacy, with reference to the rule of world trade, of national regulations is still represented by the SPS (*Sanitary and PhytoSanitary*) and TBT (*Technical Barriers to Trade*) Agreements within the WTO and by the rules of the *Codex alimentarius*.

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[20] In any case, it is worth remembering that the technique of risk assessment, management and communication (Risk Analysis), developed since the 1970s, is today governed by a body of scientific rules and regulations drawn up by Codex Alimentarius and WHO which, over time, has become increasingly organic and adherent to scientific developments. This was remembered by V. Sbervegliери, A. Pulvirenti, P. Giudici, 'Della valutazione quantitativa ai modelli di previsione dei rischi ignoti' in L. Foffani, A. Doval Pais, D. Castronuovo, *La sicurezza agroalimentare nella prospettiva europea* (Giuffrè, 2014) 4.

[21] See also E. Sirsi, 'Le regole degli OGM nello spazio globale: un'agenda per i governanti del futuro' (2010) 3 *Riv. dir. agr.* 469.

[22] E. Sirsi, *In tema di etichettatura dei prodotti geneticamente modificati* (n. 1) 644.

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Consequently, institutional debates on the topic have become commonplace in recent years. In 2017, for example, the Italian Committee for Biosafety, Biotechnology and Life Sciences started a reflection on NBTs in order to foresee possible scenarios and suggest appropriate institutional choices[23]. The classification that distinguishes *Conventional Breeding Techniques* (CBT), *Established Techniques of Genetic Modification* (ETGM) from *New Breeding Techniques* (NBT) was adopted. NBTs, in turn, encompass a wide variety of other techniques that are either a refinement of CBTs, or are used in combination with ETGM. The most promising NBTs are those that allow the correction or revision of the genome (so-called *genome editing*) to obtain precise modifications of the DNA sequence, which can vary from point mutations (modification of one or a few nucleotides) to the insertion of genes from scratch. The genome editing process was already possible for several years in an inefficient way. It has been recently greatly improved and has literally exploded in the last five years with the exploitation of RNA-dependent nucleases, typical of the bacterial system CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) and similar systems[24].

As already mentioned, genetic modifications induced in organisms through genome editing, although often derived from genetic engineering techniques, are in many cases indistinguishable from those obtained by conventional methods of mutagenesis, or resulting from spontaneous mutations and therefore do not involve greater risks to health and the environment and often involve also undesired mutations (so-called "off target") increasingly documented by the scientific literature.

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[23] National Committee for Biosafety, Biotechnology and Life Sciences, New breeding techniques (NBT): 1- The position of the main Italian stakeholders (n. 1) 17.7.2017, available at: *http://presidenza.governo.it/biotecnologie/documenti/new_breeding_techniques_NBT.pdf*

[24] It is useful to remember that today the most discussed applications of the CRISPR technique are in the field of human research, aimed at modifying the human genome. It is recent the news of the birth of two Chinese twins born with DNA modified through this technique to produce a mutation on the CCR5 gene and make them more resistant to HIV. See D. Cyranoski, 'Baby gene edits could affect a range of traits. Gene targeted for its role in HIV is linked to increased severity of other infectious diseases — and has implications for learning in mice' (2018) 12.12.2018 *Nature,* available at: *https://www.nature.com/articles/d41586-018-07713-2.*

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As we will see later, in the light of recent European documents, the vision of the Bioethics Committee appears to have been revised, since it hoped that each plant variety produced through NBT would be regulated on the basis of the character or characters modified or introduced and in relation to the possible increased risk to health and the environment compared to the risk commonly associated with the plant from which it originates, since «the impact on human health and the environment depends on the genetic makeup of the plant and not on the process by which this genetic makeup was obtained»[25].

As it is well known, the questions of definition are not valuable in themselves, but because the main regulatory coordinates applicable depend on them. As detailed below, in Europe, the ad hoc regulation of the production and marketing of food and seed containing GMOs originated in the 1990s[26], and consists of stringent legislation to ensure the safety of food and feed for health and the environment; consumers' choice between GMO and conventionally-produced food; and the functioning of the internal market, once authorized. Once classified as such, the authorization of GMOs (which took place at the European level) can be subject to possible restrictions: each Member State can deny the circulation of GMOs within its territory on the basis of requirements other than environmental and health ones without, therefore, having to base its choices on the evaluation of information emerging from risk assessment processes. In general, this legislative choice seems to be informed by the broader and transversal vision introduced with the Europe 2020 strategy, according to which European policies are called to respond to the three parameters of ethical acceptability, sustainability and social desirability[27].

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[25] Comitato nazionale per la Biosicurezza, Biotecnologie e Scienze della Vita, *Le new breeding techniques (NBT)* (n. 1) 7.

[26] The first directives are: Council directive no. 90/219/EEC on the contained use of genetically modified micro-organisms [1990] OJ L 117, p. 1-14, and Council directive no. 220/90 EEC on the deliberate release into the environment of genetically modified organisms [1990] OJ L 117, p. 15-27.

[27] These are the guiding principles of the process that underpins the so-called *Responsible Research and Innovation*. R. Von Schomberg, 'A vision of responsible innovation', in R. Owen, J. Heintz, J. Bessant, J. Wiley (eds.), *Responsible Innovation* (Wiley, 2013). In any case, member states would be required to justify the compatibility of their *opt-out* measures with EU law and the principles of proportionality and non-discrimination between domestic and non-domestic products.

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In any case, once authorized, a GMO, or a product resulting from other biotechnological processes that the legislator decides to equate with it, is subject to a regulatory framework is stratified and complex[28]. In short, the regulation differs in consideration of the techno-scientific process applied to obtain the product: genetic engineering, on the one hand, and all other technologies (organic chemistry and biology; nanotechnology; synthetic biology etc.) on the other. To the food derived from the first one are dedicated Reg. 1829/2003 EC and 1830/2003 EC (now under revision, following the Commission's Political Guidelines Communication of 15.7.2014[29], to extend to GMO food the approach adopted by EU dir. n. 412/2015 on seeds). The second category, on the other hand, is covered by Reg. 2283/2015 of the European Parliament and of the Council of 25.11.2015 on novel foods, or novel foods, which replaces the previous Reg. 258/97[30]. GMO cultivations, on the other hand, are the focus of Dir. 18/2001 EC considered "horizontal" legislation due to the fact that the requirements applicable to marketing apply to all GMOs outside of those covered by the sectoral framework[31].

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[28] A first reconstruction is offered by M. Ferrari, U. Izzo, *Diritto alimentare comparato* (Il Mulino, 2012) 167. For a summary of food legislation in European Union law and international treaties, see F. Casucci, P. Saccomanno, 'Il diritto agroalimentare' in GA. Benacchio, F. Casucci (eds), *Temi e istituti di diritto privato dell'Unione europea* (Giappichelli, 2017) 69.

[29] Commission Communication (EU) 1286/2014 on Guidelines on the application of Regulation of the European Parliament and of the Council on key information documents for packaged retail and insurance-based investment products [2017] OJ C 218, p. 11-14.

[30] *Novel foods* is an expression referring to any food or ingredient that was not consumed to a significant degree within the European Union until May 15, 1997. In the list of *Novel foods* we find all those products or ingredients made from microorganisms, fungi and algae, plants, animals or parts thereof (including insects), foods with new or modified molecular structure or resulting from a new production process or made from engineered nanomaterials, and finally vitamins, minerals and other substances not used before the entry into force of the new regulation (GMO foods are excluded when and to the extent that they are used as food enzymes, food additives and flavorings and extraction solvents). With the entry into force of the new European Parliament Regulation (EU) 2015/2283 of the European Parliament and of the Council No 1169/2011 on novel foods, amending Regulation of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2018] OJ L 327/2015. It fully repeals the old regulation, a special Union List of authorized novel foods has been established; 90 new foods have been approved within our market; and a more streamlined and faster approval process, reducing the waiting time from when you send your request to when you get an approval response.

[31] N. De Sadeleer (n. 2) 221.

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Depending on the framework, of course, different procedures for approval, authorization, labeling, traceability and marketing of food are derived.

The EU policy on GMOs is inclusive as it copes with the development of GMOs, the progressive release into the environment, the general cultivation and seed production, marketing, labelling, enforcement and the entire agro-food chain, from bottom up to the final consumption by humans and animals.

In 2011, upon request of DG SANTE, the Joint Research Center reviewed the state-of-the-art of some of the emerging new plant breeding technologies, their level of development and adoption by the breeding sector and the prospects for a future commercialization of plants created by these techniques. Additionally, with support of several experts, the challenges for the detection of organisms developed through these techniques were evaluated.

But the most disputed phase of the debates regarding the regulatory framework of NBTs arose following the interpretative ruling of the European Court of Justice C-528/16 of July 25, 2018 to which we refer in the next paragraph for a more extensive discussion.

3. European trajectories in the regulation of the agri-food biotechnologies after the CJEU C- 528/16 judgement

Crucial intervention in the regulation of emerging biotechnologies took place when the Court of Justice of the European Union ruled on the interpretative question regarding the classification of organisms obtained through the new techniques of mutagenesis: it ruled that organisms obtained by new mutagenesis techniques in contrast to conventional mutagenesis techniques "that have conventionally been used in a number of applications and have a long safety record", are not exempted from the GMO legislation[32].

[32] For a more detailed analysis of the CJEU decision see G. Guerra, 'Sul rapporto sicurezza - innovazione nel diritto agroalimentare europeo: tra «elefanti nella stanza» e «tigri di carta»' (2019) 2(II) *Nuova giur. civ. comm.* 394.

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In summary, the Court had been said of the matter following an appeal by the French *Conseil d'État*[33], brought by the transalpine agricultural union (the Confédération paysanne) and eight other plaintiff associations against national legislation (Article D 531-1 French Environment Code) exempting organisms obtained by mutagenesis (rapeseed varieties) from the obligations imposed by the European directive on GMOs.

According to the remarks of the French referring court, these techniques would entail risks similar to those associated with transgenesis and would allow an acceleration of modifications of the genetic heritage incomparable to modifications occurring naturally or by chance: this would lead to a multiplication of the probability of damage resulting from unintentional modifications of the genome and inherent to the properties of the obtained plant.

The Court's interpretation is based on a careful reconstruction of the systematic structure of the directive itself, which, however, only confirms, once again, the practical incidence of the assessment of the technological process (some mutagenesis techniques examined involve the use of chemical or physical mutagenic agents; others involve the use of genetic engineering) despite the conclusions of the Advocate General leaning towards the adoption of a product-based framework[34].

The same judges clarify that Annexes I A, part 2, and I B of Dir. n. 18/2001 EC indicate which techniques are not considered to be genetic modification, and it is relevant to note that these annexes are excluded from the revision for adaptation to technical progress, as they are not among the essential elements ex art. 27 Dir. n. 18/2001 EC. In other words, the notion of GMO has never been revised, despite the requests of biotech companies and the work of the European group which was established *ad hoc*.

The definition of GMOs under Article 2(2) of the Directive includes both techniques whose use involves a genetic modification and techniques which do not. In letter a) of the same provision it is established that a genetic modification is

[33] The French Conseil d'Etat referred the question of interpretation to the Court of Justice for a preliminary ruling in the following case. Conseil d'État, 3ème-8ème *chambres réunies*, 3.10.2016, n. 388649, pubblished on *recueil Lebon*.

[34] Opinion of the Advocate General (Michal Bobek) delivered on 18.1.2018.

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obtained at least through the use of the techniques listed in Annex I A, part 1, which does not expressly cover those of mutagenesis.

Notwithstanding, the possible inclusion of NBTs in Annex I A, part 1, is not to be overruled, as the list is not exhaustive. In summary, we can infer that the combined provisions of art. 2, paragraph 2, letter b), Dir. No 18/2001 EC and Annex IA, Part 2, mutagenesis is not included among the techniques that do not involve genetic modification. On the contrary, it is expressly mentioned among the techniques involving genetic mutation, in the list of the Annex dedicated to the organisms to be excluded from the scope of the Directive (Annex IB and art. 3.1).

In order to unravel the knot, the Court proposed a re-reading of the provisions in light of the context and purpose of the legislation: the general formulation of mutagenesis does not provide sufficient guidance as to the specific types and methods of mutagenesis that the legislature intended to exclude from the application of the directive. And it is precisely in view of the context that the Court makes one of the central findings[35]: the Directive does not cover organisms obtained through certain genetic modification techniques used "conventionally" in various applications with a "long tradition of safety." In many countries, for example, maize produced by conventional techniques of mutagenesis does not fall within the scope of the legislation on GMOs. The latter, therefore, applies in principle only to mutagenesis techniques involving modification of genetic material according to methods developed after the adoption of the directive, whose risks could be similar to those resulting from the production and dissemination of GMOs through transgenesis[36].

However, although characterized by a long tradition of safety, even conventional mutagenesis techniques could be subject, by virtue of the decentralization of choices in the field, to the same obligations provided for GMOs, since States are free to adopt measures to subject them to the obligations provided for GMOs, in compliance with European rules protecting the free movement of goods (ex articles 34 to 36 TFEU).

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[35] See paragraph 31 of the Court of Justice. Case C-535/15, *Pinckernelle* [2017] available at *www.curia.europa.eu*.

[36] Thus, noted in paragraph 48 of the judgment under review.

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The interpretative solution of the Court has provoked various reactions. The accredited scientific literature has from the outset expressed many doubts, since the judges, thus establishing, subject the "results" of the NBT to onerous pre-market evaluation tests in the absence of scientific evidence to outline the hypotheses of dangers, identifying, instead, as the only danger that of concretely preventing Europe from being able to easily disseminate technologies that contribute decisively to the problem of food security and positive impact on the environment[37].

The consequences of the Luxembourg decision are different. The "frozen" interpretation of the Court of Justice, according to which, by invoking the precautionary principle, only those safe (conventional) techniques that were regularly used at the time of the adoption of the GMO directive, fall under the exemption of mutagenesis, leaving unaffected the possibility of prohibiting them on the basis of the operation of the opt-out clause, does not contribute to a solution.

After all, the operational solution - conducted on the basis of traditions, and many other elements related to social change and national cultures - may, in other words, lead to interpret the declaratory rule in a dissociated way from what science indicates about the real degree of uncertainty that characterizes the level of risk to health and the environment inherent in biotechnology.

The decentralization of the choices regarding the authorization of products derived from genetic engineering could, consequently, lead to submit to the onerous procedures of evaluation and authorization provided for GMOs even those techniques of varietal improvement, considered safe by the scientific literature.

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[37] In Europe, the EPSO documents are fundamental guidelines: the *European Plant Science Organisation* bringing together 28.000 European Scientists (available at: *http://www.epsoweb.org/file/2038*); and EASAC documents (available at: *http://www.easac.eu/fileadmin/PDF_s/reports_statements/Easac_14_NBT.pdf*). See also the European Plant Science Organization (EPSO) document On the ECJ Ruling regarding mutagenesis and the Genetically Modified Organisms Directive, Brussels, 26.7.2018 (available at *www.epsoweborg*). With this document the EPSO had already expressed the scientific evidence about the advantages and strengths of NPBTs in the paper *Crop Genetic Improvement Technologies*, Brussels, 26.2.2015 (with updates of 18.12.2015 and 12.1.2017), available on the same website. Opinions from many other scientific organizations follow the same direction. For a reconstruction, please refer to the paper of the *National Committee for Biosafety, Biotechnology and Life Sciences, The New Breeding Techniques* (NBT) (n. 1).

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What should be carefully considered here are the developments of the debate in the post-judgment phase.

In October 2018, the Joint Research Centre was entrusted with the mandate on behalf of the EU Commission (DG Sante) to work out the implications of this ruling in order to identify such organisms. The document addresses issues concerning the new analytical challenges for the detection, identification and quantification of genome-edited food and feed products of plant origin[38], considering the compliance with the GM food and feed legislation, including the prerequisites for method validation as part of the GMO authorization procedures, and to the Official Controls Regulation provisions on the routine testing of food and feed by the enforcement laboratories.

Furthermore, in November 2019, the Council of the European Union requested the Commission in Decision 2019/1904[39] to submit, by April 30, 2021, "a study in light of the judgment of the Court of Justice in Case C-528/16 concerning the status of new genomic techniques in Union law." First, based on this study, it is important to emphasize the distinction based on time limits the importance NGTs are defined as techniques that can modify the genetic material of an organism and that have emerged or have been developed since 2001, when the current GMO legislation was adopted.

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[38] European Network of GMO Laboratories (JRC - EU Commission), Detection of food and feed plant products obtained by new mutagenesis techniques, Report endorsed by the ENGL Steering Committee [March, 2019].

[39] Council Decision (EU) 2019/1904 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study [2019]. The expected study would have dealt with: (a) a state-of-play on the implementation and enforcement of the GMO legislation, as regards NGTs, based on 1) contributions from targeted consultations of the Member States and stakeholders (to consult the consultation procedure see: https://ec.europa.eu/food/plant/gmo/modern_biotech/stakeholder-consultation_en); 2) work of the European Union Reference Laboratory, together with the European Network of GMO Laboratories, on the detection of products obtained by new mutagenesis techniques (https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf); (b) information on the status and use of NGTs in plants, animals and micro-organisms for agri-food, industrial and pharmaceutical applications. Moreover, an overview on the risk assessment of plants developed through new genomic techniques, prepared by the European Food Safety Authority (EFSA, https://www.efsa.europa.eu/en), based on its own previous and ongoing work and on work carried out at national level.

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Finally, the response came last April, 29, when the EU Commission published the staff working document's about the *Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16* (from now on: the Study)[40]. In sum, the study confirms that organisms obtained through new genomic techniques are subject to the GMO legislation. However developments in biotechnology, combined with a lack of definitions or the ones that resulted unclear are still giving rise to ambiguity in the interpretation of some concepts, potentially leading to regulatory uncertainty[41]. Consequently, the current regulatory system involves implementation and enforcement challenges in the EU for NGT and also underlined the need for flexibility and proportionality in the related risk assessment.

What is also relevant it is the fact that the study recognized the synergic role of the analysis of the ethical and societal implications of gene editing that is being developed by the European Group on Ethics in Science and New Technologies[42]. This is due to the fact that based on the findings of the Study most of the ethical concerns raised relate to how these techniques are used, rather than the techniques themselves.

The Opinion's area-specific analyses are complemented by overarching considerations on long-debated questions revived by genome editing, notably about

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[40] Commission Staff Working Document (EU Commission) Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, Brussels, [2021] 92 final, available at: https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf.

[41] Idem, p. 2 of the document.

[42] The European Commission requested the EGE to submit an Opinion and recommendations on genome editing, thereby following up on the EGE's Statement on Gene Editing, issued in January 2016 (EGE, 2016, Statement on Gene Editing, https://ec.europa.eu/info/publications/egestatements_en). On March 19, 2021 the European Group on Ethics in Science and Technologies published its Opinion on the ethics of genome editing analysing ethical questions raised by the application of genome editing in humans, animals and plants, and hence spans health, research, agriculture and environmental aspects. The EGE is calling for a wide-ranging and inclusive societal debate on genome editing, for efforts towards joint monitoring and learning with regard to both regulatory and scientific developments, and for international engagement towards global governance. This will be functional to examine how specifically the EU can and should shape governance and policies for genome editing. The Opinion aims at examining how specifically the EU can and should shape governance and policies for genome editing. More information available at: https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/ege_en#latest.

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the different meanings that ought to be attributed to humanness, naturalness and diversity.

EGE is invoking a wide-ranging and inclusive societal debate on genome editing, for initiatives towards shared team monitoring and learning pertaining to both regulatory and scientific developments, and for international engagement towards global governance.

The combined reading of all these documents is the clearest sign of a change of approach in the regulation of the new agri-food biotechnologies where the risk assessment and the preparation of regulatory response models are at the crossroads of a multiplicity of disciplinary contributions (scientific, sociological, etc..) that affect the development of the notion of risk[43].

As «public perception of new technologies is key to their market uptake»[44], it is now a given that the acceptance of a technology is also determined by the perception of its potential benefits: most people question the need and usefulness of precision agri-food biotechnologies[45].

To capture the impact of the perception of the social datum of risk in regulatory choices, an important contribution is offered by the economic analysis of law. In the report "On Mandatory Labeling, with Special Reference to Genetically Modified Foods"[46], the authoritative American jurist Cass Sunstein analyzed, through the lens

[43] The relationship scientific information-legal rule-consumer trust is conditioned by the impact of many factors that must be understood and included from the beginning in regulatory processes. The impact of the social perception of risk, for example, is a fact that the European legislator is increasingly taking into account in the choice of regulatory techniques used: more and more legislative procedures are inspired by participatory and inclusive processes of different actors, such as consumers, from the earliest stages of preparing the relevant legal documentation.

[44] Page 4 of the Study.

[45] A. Ronteltap, J.C.M. van Trijp, R. J. Renes, L. J. Frewer, 'Consumer Acceptance of Technology-based food innovations: lessons for future of nutrigenomics' (2007) 49 *Appetite* 1; P. Slovic, 'Perception of Risk' (1987) 236 *Science* 280.

[46] C. Sunstein, *On Mandatory Labeling with Special Reference to Genetically Modified Foods*, Report del 9.10.2016.

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of this discipline, the obligation introduced in the USA - with the federal *GMO Labeling law* of 29.7.2016 - to indicate on the label the presence of GMOs[47].

The report starts from the observation of the absence of reliable scientific data to attest to the risks inherent in GMOs[48], and asks when governments should introduce mandatory information content and when mandatory information has desirable consequences for social welfare, as well as how to measure these effects. Another important issue raised by the report questions the right of the consumer to know the ingredients for the sole purpose of making food choices aimed at fulfilling his or her personality (benefit): in particular, it asks whether it is sufficient to justify additional precautionary measures, i.e. ad hoc labels (cost), even in the absence of scientific evidence about the risk of health damage related to GMOs. Sunstein notes that based on the data obtained from the interviews, mandatory labeling for GMOs was introduced "because members (i) demanded it without really being interested; and (ii) believing that GMOs are dangerous not based on existing scientific data"[49].

Understanding, then, the impact of the socio-demographic factor on the acceptance of new technologies is a key factor for policymakers to formulate meaningful government proposals, particularly in Europe, where options vary widely depending on the member state considered. In the collective imagination, for example, European consumers tend to be *risk-adverse*[50]. Despite the efforts of public

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[47] *National Bioengineered Food Disclosure Standard*, Pub. L. No. 114-216 (2016) (*codified at 7 U.S.C. § 1621 et seq.* (2016).

[48] Given that the scenario excludes irreversible and catastrophic damage from Gmos, the precautionary approach through *labels* or restrictions would be appropriate. The report notes that: «*the force of this response depends on the science: if there is a small or uncertain risk of serious harm, precautions may indeed be justified. If the risk is essentially zero, as many scientists have concluded, then precautions are difficult to justify. The discussion, though focused on GM foods, has implications for disclosure policies in general, which often raise difficult questions about hard-to-quantify benefits, the proper use of cost-benefit balancing, and the appropriate role of precautionary thinking*».

[49] Report, 5.

[50] The data indicating this attitude are given by Eurobarometer, *Europeans' attitudes towards animal cloning, analytical report. Survey requested by Directorate General Health and Consumers and coordinated by Directorate General Communication (European Commission)*, in *Flash eurobarometer*, Vol. 238, Brussels, The Gallup Organization, October 2008. However, authoritative American doctrine holds that European consumers would no longer be averse to the risk of American consumers, see C. Sunstein, *Il diritto della paura: oltre il principio di precauzione* (Il Mulino, 2010) 26.

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authorities to increase their level of confidence in food safety, some new technologies - regardless of their potential benefits - have less uptake in society for this very reason.

This is why, according to what the EGE observed, ethical and moral concerns are more frequent and vary according to the geopolitical context and the background of the citizen, all of which undermine the solution that has been opted for years, concerning the identification of the threshold of safety (*safe enough*). Writes the panel:

«*debates about genome editing often focus on the question about the conditions that would render it 'safe enough' for application. The Opinion draws attention to the importance of nuancing and resisting this framing, as it purports that it is enough for a given overall level of safety to be reached in order for a technology to be rolled out unhindered, and it limits reflections on ethics and governance to considerations about safety. Much to the contrary, ethics should serve to tackle broad governance questions about how technologies can serve our common goals and values, and not be limited to providing a 'last step' of 'ethics clearing' of a technology*»[51].

Understanding consumers' perceptions of risks and benefits, also based on socio-demographic and cultural data, is therefore a crucial step for the success of techno-scientific progress[52]. These considerations are of fundamental importance as they will also influence the way of considering and regulating the institutions of agri-food law in general, for example, the fact that scientific information alone about agri-food technologies does not, therefore, automatically lead the consumer to the acceptance of technological risk[53].

The still uncertain framework in search of a solution at the European level reverberates at the national level. Member States made a variety of comments in relation to NGTs and established GMO techniques. They highlighted current problems in the GMO legislation and/or argued that it is obsolete, and called on the

[51] European Group on Ethics in Science and New Technologies (EU Commission), *Opinion on Ethics of Genome Editing*, Opinion (n. 8).

[52] L.J. Frewer, C. Howard, J.I. Aaron, 'Consumer Acceptance of transgenic crops' (1998) 52 *Pesticide Science* 388.

[53] C.M. Bruhn, 'Consumer acceptance of food innovations' (2008) 10(1) *Innovation: Management. Policy & Practice* 91.

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Commission to clarify and/or define terminology and to clarify the legal status of NGTs in the current framework. The Study reported that most of the Member States highlighted the need to develop detection methods for NGts integrating sustainability criteria[54].

Last January four decrees (nn. 208, 209, 211 e 212)[55] on issues ranging from Nbt to the marketing of seeds were discussed at the Italian Agriculture Commission of the House. Legislative decrees on which the Senate Agriculture Committee already expressed positive feedback last December. The Agriculture Committee of the House has slowed down the push to introduce New Breeding Techniques in Italian fields. It did so by approving the opinion schemes on the four legislative decrees with reservations[56].

Equally significant are the initiatives undertaken by the British government, among the first in the post-Brexit period. The Department for Environment Food and Rural Affairs has recently launched a consultation on gene editing that confirms the openness towards this type of technology in agriculture, and expresses concern about possible issues of "access to the EU market and compliance with the EU regulatory system", if the EU opts instead for a more restrictive regime[57].

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[54] See page 49 of the Study document.

[55] The Italian decrees are available at: https://www.camera.it/leg18/99?shadow_organo_parlamentare=2813

[56] In other countries too, uncertainties remain. The French government is also considering how to respond to a ruling by the country's top administrative court requiring it to change its mutagenesis regulations in line with the EU court's decision, as France is the EU's largest agricultural producer and among EU members to have banned cultivation of GMO crops. England's farming minister announced earlier this month a public consultation on gene editing in agriculture, saying Britain's exit from the EU allowed it to set its own rules.

[57] Currently GMOs are defined in section 106 of the Environmental Protection Act 1990 as amended by Regulation 4 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (SI 2002/2443); techniques of GM are described in regulation 5.

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According to the results of the consultation, the Department may change the legislation to amend the definition of a GMO as it applies in England during the post- Brexit period[58].

4. The main regulatory models and their foundational principles: (a) the substantial equivalence…

The increasingly transnational nature of agri-food issues implies the interest in the regulatory solutions adopted by different countries in order to classify modern biotechnologies[59]. On the one hand, it is interesting to understand the different ways in which legal systems balance technological and scientific progress and safety; on the other hand, this is useful to assess the impact of an uneven legislative framework in the dynamics of transnational trade in seeds and food derived from these techniques.

The models of *governance* and regulation of genomics-related matters vary, therefore, depending on the geopolitical contexts, and for what has been said before it should be borne in mind that the *risk analysis* in countries with different socio-sanitary realities has imposed inevitably different definitions of risk on the basis of the social and political perception of the same[60]. Each of these different socio-

[58] Cfr. Consultation procedure is available at: https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/. The consultation, confirmed by the UK Environment Secretary George Eustice at the Oxford Farming Conference on Wednesday (7 January), will focus on preventing gene-editing (GE) organisms from being regulated in the same way as genetically modified (GM) crops, according to a statement released by the UK government.

[59] It is meaningful that the Commission staff's working document on the status of new genomic techniques (see footnote 39) confirms that notwithstanding the considerable interest in EU, the most of the development is taking place outside the EU (page 2 of the document).

[60] See V. Sberveglieri, A. Pulvirenti, P. Giudici, 'Della valutazione quantitativa ai modelli di previsione dei rischi ignoti' L. Foffani, A. Doval Pais, D. Castronuovo, *La sicurezza agroalimentare nella prospettiva europea* (Giuffrè, 2014) 3. It has to be noted that «the regulation of GM crops has been challenges as inadequate, even biased, and in some settings as Brazil, India, and Mexico the planting of certain GM crops has been at times suspended, while in other regions, such as Europe, governing bodies have struggled to resolve the dilemma of how to stimulate the development of biotechnological innovation for the benefit of the economy and the environment while maintaining public legitimacy» (P. Macnaghten, M.G.L. Habets (n. 13).

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technological contexts affects the nature of the activities which are regulated as well as the content of the regulations that are enacted[61].

The different policy options depend, in fact, on the historical background of the central notions of environment and health, but also on the role that the legal systems attribute to the subjects entitled to perform a risk assessment with characteristics of third party, as well as the data that should be used and the way in which they should be collected. All of this influences the substantial differences in the *policies* of the different legal systems on biotechnology.

Accepting a good degree of simplification, one can distinguish three approaches circulating in the member states and non-European states: (i) the one based on the discipline of the techno-scientific process used to obtain the product; (ii) the one focused on the final product; and (iii) the one based on the prior request for assessment and definition of the discipline applicable to the competent authority[62].

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[61] On this point see an interesting paper that develops a comparative framework for biotechnology policy analysis and applies this framework to help understand the evolution and differences in the regulatory regimes related to agri-food genomic innovations found in six countries (Italy, Spain, Australia, New Zeland, Canada and the US). Findings show that these governments have fostered different types of regulatory regimes over the last quarter century that are closely connected with the manner in which governments have pursued either promotional or precautionary orientations towards new technologies; and second whether regulatory policy-making has been driven by state or public actors and interest. See M. Howlett, A. Migone, 'Explaining local variation in agri-food biotechnology policies: "green" genomics regulation in comparative perspective' (2010) 37(10) *Science and Public Policy,* 781-792.

[62] In the workshop organized by the Institute for Prospective Technological Studies (IPTS) in 2011, the different approaches used were compared, inviting representatives from Argentina, Australia, Canada, the European Union, Japan and South Africa. Countries where GMO crops are very widespread have initiated a phase of involvement of scientific experts for the assessment of the comparability of GMO-NBT products. The results have led to identify which mutagenicity specifications lead to products similar to those obtained with transgenesis, and which are not, and these situations are transposed in the *Gene Technology Act* of 2000 (Act No. 169 of 2000) and in the Gene Technology Regulations 2001 (Australian Government, Department of Health, Office of the Gene Technology Regulator, Gene Technology Regulations 2001 (made under Gene Technology Act), as amended on 16 July 2016, available at https://www.legislation.gov.au/Details/F2016C00615). Other orders, on the other hand, introduce a mixed system between the two models, or with some peculiarities: the Japanese system, for example, follows the American model based on the regulation of the product and the logic of substantial equivalence, which, however, is intended to qualify the comparator product which already exists on the market, and not to introduce a presumption of safety. The existence of a similar product on the market does not, in fact, prevent the analysis of further scientific data that

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In brief, the regulatory models adopted by the various countries differ in relation to: the choice of administrative or legislative approach; the legislative technique employed (general or specific rules); the option for «product» or technological «process» regulation. The main contrast remains between the preventive-precautionary approach and that based, instead, predominantly on post-market risk management tools, such as controls and sanctions, which is promotional.

This last distinction is significant[63], mostly from a historical perspective, since even in light of the considerations made in the *Study*, the debate should focus on the definition of ad hoc *risk assessment* systems that are attentive not only to the type of technology employed, but above all to its specific uses.

Essentially, it is exemplified in two experiences: the European experience, historically developed around the idea of process, and the North American and Canadian experience for which the decisive criterion is the end-product rather than the manufacturing process of foods, and consequently the process according to which a food was produced is irrelevant[64].

These models are based on two different principles: the exquisitely European principle of precaution, and the North American principle of substantial equivalence.

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could lead to a ban on GMO products (in 2003 the Japanese government signed the Cartagena Protocol on Biosafety, introducing the law of 19.2.2004). Possible exceptions for organisms obtained from cloning. Some non-eu countries determine the legal status of NBT by a case by case pre-submission consultation (see more information in the Study, page 24 of the document). Among the different countries that follow the European model, there is that of South Africa, which, with the *Genetically Modified Organisms Act* (G 18029) meets as many similar defining problems (*Government Gazette*, Vol. 383, No. 18029, 23 May 1997).

[63] Cfr. M. Lusser, E. Rodríguez Cerezo, 'Comparative regulatory approaches for new plant breeding techniques. Workshop proceedings (European Commission, JRC Technical Report EUR 25237 EN, 2012)' (2013) 30(5) *New Biotechnology*, 10.

[64] For a preliminary discussion of the distinction process-based and product-based approaches and its weakness see M. Ferrari, U. Izzo (n. 28); and also M. Ferrari, 'Sicurezza alimentare e nuovi prodotti alimentari**',** in G. Guerra, A. Muratorio, D. Ruggiu (eds), *La biologia sintetica in questione: una prima analisi giuridica*' (Notizie Di Politeia, 2014) 89.

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Due to the importance of this different source of inspiration, I will dedicate a brief consideration of each one starting from the substantial equivalence and dedicating the following paragraph to precaution (see § 5).

Substantial correspondence was designed in the 1990s as a risk assessment method. The principle emerged at an international level and was thereafter applied at a national level: the Organization for Economic Co-operation and Development (OECD) wanted to develop a risk assessment method that would liberalize trade in biotech products and incentivize regulatory harmonization[65]. It was then adopted by the OECD and other international organizations. A determination of substantial equivalence between biotech and conventional foods minimizes the regulatory obstacles at an international level by standardizing the risk assessment parameters throughout countries.

The principle is rooted in American policy on the subject, which has been favorable to biotech development since the 1980s. In fact, the first *Coordinated Framework for the Regulation of Biotechnology* published by the *Office of Science and Technology Policy*[66], then updated in 2017 by the *National Strategy for Modernizing the Regulatory System for Biotechnology Products* which provides guidelines to the three authorities responsible for regulating food safety[67]: *Food and Drug Administration* (FDA); *US Department of Agriculture* (USDA); and *Environmental Protection Agency* (EPA)[68] dates back to that period.

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[65] See OECD, *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles* (OECD, 1993), p.14. The concept was first used in a US document. See FDA, *Statement of Policy: Foods Derived from New Plant Varieties* (1992) 57 Fed. Reg. 22984.

[66] Executive Office of the President, Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 FR 23302, at 23302-23303 (June 26, 1986), available at: *http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf*.

[67] The document *Modernizing the Regulatory System for Biotechnology Products* is available at: *https://docs.wixstatic.com/ugd/ea7add_3e720bb3bd954da79ee611885d68ea91.pdf*. See also the *National Strategy for Modernizing the Regulatory System for Biotechnology Products, Products of the emerging Technologies Interagency Policy Coordination Committee's Biotechnology Working Group*, 2016.

[68] The institutional architecture in this area is notoriously fragmented compared to the European one due to the different distribution of competences: while in the American system the functions of *risk assessment* and *risk management* are the responsibility of the same Authority, or Agencies, which are in turn competent for different subjects assigned to each of them.

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The basic approach was to consider the current already operational regulations on health and safety protection as sufficiently appropriate[69], as they were certain and immediate for companies pertain to the hypothetical introduction of a new *ad hoc* law. In product-based model[70], there is no specific regulation dedicated to plants and food resulting from the use of biotechnology: these products are presumed to be substantially equal to traditional ones, in the absence of evidence to the contrary.

As regards the object whose safety is assessed, the final characteristics of the new product are compared with the presumed equivalent product already on the market, on the basis of the validity procedures of the scientific community[71].

If substantial equivalence is present between two foods, no further premarket authorization or specific labeling is required for biotech foods[72]. Substantial equivalence, as a scientific concept, consists of two elements. First, substantial equivalence is based on an assumption of risk equivalence between biotech and conventional foods. The goal is not to establish an absolute level of safety, but to ensure with "reasonable certainty" that no harm to public health or the environment will result from novel foods. The reasoning is that modern biotechnology does not automatically produce foods that are "less safe than those developed using conventional techniques." In other words, biotech foods are not risk-free; they simply pose the same kinds of human health and food safety risks as conventional foods. Substantial equivalence involves a comparative analysis between biotech and conventional foods. One compares the chemical composition between the biotech and conventional food, as well as molecular, agronomic, and morphological

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[69] G. Fernández Albújar, B. van der Meulen, *The Legal GMO Concept Reassessment of the GMO definition in the light of new breeding techniques (NBTs)* (n. 1)

[70] See *amplius* M. Ferrari, U. Izzo (n. 28) 191.

[71] The FDA proceeds to a *pre-market approval* only when the new food differs substantially from the traditional one regarding its composition, structure or function. This can happen, for example, when novel food offers features normally not present in the traditional product that can trigger allergic reactions or other disorders. In the case of *novel foods* it often happens that the food has characters that are not present in its natural or traditional equivalent, it will have to be considered adulterated according to the *Food, Drug and Cosmetic Act (FDCA)*, 1992

[72] See Food and Agriculture Organization (FAO), World Health Organization (WHO), *Expert Consultation on Biotechnology and Food Safety* (FAO/WHO, 1996); and FAO/WHO, *Expert Consultation on Foods derived from Biotechnology* (FAO/WHO, 2000).

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characteristics, and nutritional (or anti-nutritional) components. In the early 2000s, the concept was further refined by the 2000 FAO/WHO Joint Expert Consultation on Foods Derived from Biotechnology. The goal is to determine whether the biotech food presents new or increased risks compared to its conventional counterpart, without affecting the health or nutritional status of consumers. The framework for this element of substantive equivalence benchmarking is more neutral and does not favor biotech foods. The FAO and WHO have also confirmed that substantial equivalence is "the most practical approach to address safety assessment" of biotech foods[73]. It is part of the safety assessment of biotech foods and this assessment is framed as a positive scientific approach that favors these types of foods. However, it seems bizarre to assume that a new type of food should be considered as safe as a traditional food that would have been consumed within the last few hundred or thousand years. A related principle to that of substantial equivalence and crucial in the evaluation is based on the notion of GRAS, which is *generally recognized as safe*[74]. According to the *Code of Federal Regulations*, a substance is generally recognized as safe based on the assessment of qualified experts and experience in evaluating the safety of substances directly or indirectly added to food. These evaluations are based on risk assessment processes or, in the case of substances used in foods prior to 1958, on data already available on the consumption of those foods, and food additives that are considered generally safe should not be subjected to pre-market approval. This principle is rooted in American policy on the subject, which has been favorable to biotech development since the 1980s, when the first Coordinated Framework for the Regulation of Biotechnology, published by the Office of Science and Technology Policy was published[75].

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[73] FAO/WHO, *Expert Consultation on Biotechnology and Food Safety* (1996), p. 4 of the document.

[74] Based on the rule *Generally Recognized As Safe (GRAS)* expressed in the *Code of Federal Regulations* (part. 182), available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=182*.

[75] About the Coordinated Framework for the Regulation of Biotechnology available at: https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about/about. It was updated in 2017 by the National Strategy for Modernizing the Regulatory System for Biotechnology Products, which provides guidelines to the three authorities responsible for regulating food safety.

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On the whole, not only is substantial equivalence a scientific assessment but it is also strategic throughout the regulatory phase of biotech food regulation. If biotech foods are substantially correspondent to conventional foods, they are regulated likewise conventional foods. Substantial equivalence is a sort of tool for defining those new foods that do not bring up special intensive safety issues[76].

Turning back to the specific problem, the issue of the legal treatment of NBTs has been addressed in American law by the *United States Department of Agriculture* (USDA)[77] pertaining to the problem of threats to the ecosystem due to weeds. Many transgenic plants are obtained through the introduction, in a plant, of a gene derived from a weed. When this happens, the plant falls under the regulation of the USDA under the *Plant Protection Act* dedicated to import, trade and environmental protection against pesticides[78]. If a plant does not fall under the Act, then trials can be conducted without the need for a notification process. The USDA, in other words, encourages innovation in the absence of risk[79].

In any case, depending on the nature and the use to which it is destined, the plant may also be subject to the controls foreseen by other Authorities, such as the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).

Some "slowdowns" may occur as a result of these Departments or Agencies. The FDA could establish its own guidelines regarding the health risks of using genetically modified corn, or regarding the use of gene editing in animals. The latter

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[76] H. Miller, 'Substantial Equivalence: its Uses and Abuses' (1999) 17 *Nature Biotechnology* 1042.

[77] USDA, *http://www.aphis.usda.gov/biotechnology/reg_loi.shtml.*

[78] *The Plant Protection Act* (PPA part of Pub.L. 106-224) is a federal law enacted on 20 June 2000. The provisions are currently codified in 7 USCS §§ 7701 et seq.

[79] The Director of the USDA said: «*USDA seeks to allow innovation when there is no risk present. At the same time, I want to be clear to consumers that we will not be stepping away from our regulatory responsibilities. While these (plant breeding innovation) crops do not require regulatory oversight, we do have an important role to play in protecting plant health by evaluating products developed using modern biotechnology. This is a role USDA has played for more than 30 years, and one I will continue to take very seriously, as we work to modernize our technology-focused regulations*». It was reported in the *National Grain and Feed Association* del 29.3.2018, available at: *https://www.ngfa.org/newsletter/usda-issues-statement-regulation-innovative-plant-breeding-techniques-ngfa-issues-response/*.

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application is classified by the FDA as a form of gene therapy, regulated as a veterinary drug, which is subject to an onerous approval process for new drugs[80].

5….(*continued*) the precautionary logic

In line with the prominent and contexted role of the Precautionary principle in EU law, the precautionary logic has manifested itself over time in various ways in EU food system[81].

In fact, it can be noted that restrictive policies on GMOs have been pursued by the European Union through different types of legal instruments: the recourse to the mechanism of notification in the presence of harmonization measures pursuant to art. 114, § 5, TFEU; the request for authorization to introduce a ban on the use of genetically modified seed varieties listed in the common catalog; the invocation of the safeguard clause pursuant to art. 114, § 10, TFEU, the application of the principle of coexistence[82].

Among these, the safeguard clauses have represented the most significant legal instruments, wanted by the EU legislator to allow individual member states to derogate from European legislation and to maintain in force and/or introduce temporary national measures[83]. This regulatory solution has, then, undergone a major change with the adoption of EU dir. no. 412/2015: a first step towards a

[80] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine Guidance for Industry, *revision of Guidance #187*, *Regulation of Genetically Engineered Animals*, 2017, available at: *www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf*.

[81] There are a great number of studies, articles and books focused on the role of the precautionary principle (PP) in International and EU law. See J. Peel, Precaution in L. Rajamani, J. Peel (ed.), The Oxford Handbook of International Environmental Law (OUP, 2021).

[82] M. P. Genesin, 'La moratoria sulle coltivazioni transgeniche nell'ordinamento italiano: scenario attuale e prospettive future' (2015) Vol. 80/I *Resp. civ. e prev.* 714.

[83] The European legislator does not offer a definition of safeguard clauses. For a discussion of the issue please refer to A. Gratani, 'Il principio di precauzione nel diritto UE. Le misure di salvaguardia e la circolazione degli OGM (Nota a Corte di Giustizia dell'Unione europea, sez. III, 13 settembre 2017, causa C-111/16') (2017) *Riv. giur. amb.* 661-675.

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broader reform that from the matter of crops is now a source of inspiration for GMO-containing foods. The reform package promoted in the field of cultivation in 2015 is based on the opt-out rule (Articles 26-bis and 26-quater dir. no. 412/2015 EU)[84]: member states are free to take national decisions to restrict or prohibit the use of GMOs in food or feed within their territory, when they have also been authorized at European level, without having to use the safeguard clause[85]. This means that the Member State may prohibit the introduction of GM crops by invoking one or more "overriding factors" that do not conflict with the EFSA's assessment of risks to health and the environment. The "overriding factors" referred to in Art. 26-bis, para. 3, EU dir. no. 412/2015 could be invoked individually or in combination and cover a large number of reasons: a) environmental policy objectives; b) urban and rural planning; c) land use; d) socio-economic impacts; e) need to avoid the presence of GMOs in other products without prejudice to Art. 26-bis; f) agricultural policy objectives; g) public order[86].

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[84] The package adopted by the Commission on 22.4.2015 includes the following documents: a Commission communication on the review of decision-making on genetically modified organisms; a proposal for a regulation allowing Member States to restrict or prohibit in their territories the use of Gmos in food or feed (Proposal for a Regulation of the European Parliament and of the Council amending the Regulation (EC) No. 1829/2003 as regards the possibility for Member States to restrict or prohibit the use of genetically modified food and feed on their territory [2015]); a European Parliament Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of genetically modified organisms (Gmos) on their territory [2016] OJ Gen. Ser. 288/2016. The Directive entered into force on 11/12/2016.

[85] According to art. 23 dir. n. 18/2001 CE «where a Member State, on the basis of new or additional information which has become available after the date of authorization and which relates to the environmental risk assessment or a reassessment of existing information based on new or additional knowledge scientific, has reasonable grounds to believe that a GMO as or in a product duly notified and authorized in writing under this Directive poses a risk to human health or the environment, may temporarily restrict or prohibit its use or sale on its territory. The Member State shall ensure that, in the event of a serious risk, emergency measures, such as suspension or cessation of placing on the market, and public information, are implemented. The Member State shall immediately inform the Commission and the other Member States of the actions taken under this Article and give reasons for its decision, providing a new assessment of the environmental risk assessment, indicating whether and how the conditions of the authorization should be changed, or the authorization should be revoked and, if necessary».

[86] For a detailed analysis of the individual factors, please refer to De Sadeleer (n. 2).

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In this way, a variable geometry system is outlined: the solutions adopted vary according to the different national choices. Often these choices are based on the operation of the precautionary principle. On the basis of art. 7 of EC Regulation n. 178/2002, states can have recourse to the precautionary principle only when it is clear that food could pose a serious risk to human health which cannot be adequately addressed by the member state. The Commission can adopt emergency measures, in case it fails to do so, the Member State is entitled to adopt emergency measures for genetically modified food and feed[87].

With regard to this mechanism, it is important to consider the relationship between the operation of the precautionary principle and art. 34 EC Reg. n. 1829/2003 which sets the rule for the adoption of emergency measures. In the case concerning the arbitrary introduction in 2013, in Italy, of the provisional emergency measure of the prohibition of the cultivation of maize varieties MON 810, for example, the conclusions of the Court of Justice, in Case C-111/16 of 13.9.2017 recall that the application of the precautionary principle is possible only for the protection of the general interest of health[88].

The level of uncertainty of the potential risk must, therefore, be subject to constant review by the public authorities, based on any new scientific data available. For this very reason, any restrictive measure must be proportionate and provisional in order to allow for the right balance between the high level of health protection and the functioning of the internal market based on the effective free movement of food and feed. Consequently, the precautionary principle cannot be invoked in order to circumvent or modify, making less stringent, the provisions provided for by art. 34. From a combined reading of art. 34 and the precautionary principle, Member States are not allowed to adopt arbitrary emergency measures based on the sole basis of this principle. Italy would have, therefore, introduced a safeguard measure in violation of the procedure laid down in art. 54 of Regulation n. 178/2002 EC, since it is possible to resort to protectionist measures only when, in

[87] See A. Monica, 'Osservazioni a Corte Giust. UE, III Sez., 13.9.2017, causa C-111/16, Fidenzato' (2017) *Riv. it. dir. pubbl. com.* 1585. As regards, instead, the operation of the precautionary principle in relation to Directive n. 18/2001 EC, it should be noted that recital 8 refers to the principle in the development and implementation of the same.

[88] ECJ case C-111/16, *Fidenzato* [2017], commented by A. Monica (n. 87)

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the face of the non-action of the Commission, there is a "serious" and "manifest" risk to human health, animals or the environment the precautionary logic.

It is therefore necessary to fully understand the operation of the principles of precaution and prevention in the light of safeguard measures and the value of scientific evidence that underlies the presence or absence of an event-damage or an event-serious risk of damage. In this judgment, the Luxembourg judges clarify that Member States may not adopt emergency measures regarding genetically modified food and feed without evidence of a serious risk to health or the environment[89]. The precautionary principle in art. 7 of Reg. n. 178/2002 EC and the procedure for the adoption of emergency measures, regulated by art. 34 of Reg. n. 1829/2003 EC, in conjunction with art. 53-54 of Reg. n. 178/2002 EC, respond to a need to take measures in accordance with the precautionary principle. The Regulation on food safety 178/2002 EC responds to a logic of risk that is based on different assumptions: the possibility of harmful effects on health and the persistence of a situation of scientific uncertainty, as regards the application of the precautionary principle; a serious risk to human health, animal health or the environment, however, for the application of emergency measures[90]. Thus, where it is not established that a GM product is likely to pose a serious risk to health or the environment, neither the Commission nor the Member States have the power to take emergency measures such as a ban on cultivation (in this case, MON 810 maize).

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[89] The reference for a preliminary ruling concerns the interpretation of Article 34 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1) and of Articles 53 and 54 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 268, p. 1). This request has been made in the context of criminal proceedings against Mr Giorgio Fidenzato and Mr Leandro and Mr Luciano Taboga, accused of having cultivated the genetically modified maize variety MON 810, in breach of the national legislation prohibiting such cultivation. CJE, 13.9.2017, case C-111/16.

[90] See ECJ case C- 111/16. For a comment please refer to A. Gratani, 'Il principio di precauzione nel diritto UE. Le misure di salvaguardia e la circolazione degli OGM. Nota a Corte di Giustizia dell'Unione europea, (n. 83).

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Generally speaking, within EU food law, the pivotal role played by the precautionary principle in cases of scientific uncertainty for foods has compelled decision-makers to act carefully and with foresight when deciding on biotech foods, and by so doing potentially ban such foods from being marketed in the EU. It would appear that the precautionary principle has become a cornerstone in the regulation of biotech foods. For this reason, cloned and GM foods are regulated under distinctive regimes. The authorization, labelling and traceability requirements for GM foods are harmonized by two complementary regulations, the Food and Feed Regulation and the Traceability Regulation (see more § 6).

6. Lights and shadows in European legislation: blurring the line between different approaches

Among the above described framework, key observations focused on the concrete operative regulatory mechanisms depict an interplay between precautionary measures and other European rules concretely based on substantial equivalence[91].

From an historical point of view, within EU food law, the precautionary principle plays a pivotal role particularly starting from the early 2000s, when the EU regimes for biotech foods were updated and the process approach was implemented. It appears that the principle of substantial equivalence and the simplified procedure were discarded from these regimes as they were reputed too contentious and artificial. Anyway, this is not completely true as, notwithstanding the general and evident precautionary approach, a thorough analysis of the biotech regulatory regimes reveals that the older and more controversial concept of substantial equivalence is still present in the European regulation of biotech foods.

On one hand, the new and "improved" frameworks for biotech foods established by the Food and Feed Regulation and the Traceability Regulation for GM foods, and the 2015 Novel Foods Regulation for cloned foods, set much-

[91] The issue was analysed by L. Petetin, 'Precaution and equivalence: the critical interplay in the EU biotech foods' (2017) 42(6) *E.L. Rev.* 831.

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awaited, strong precautionary EU procedures. Cloned and GM foods are regulated under distinctive regimes. The authorization, labelling and traceability requirements for GM foods are harmonized by two complementary regulations, the Food and Feed Regulation and the Traceability Regulation. From 1 January 2018, the 2015 Novel Foods Regulation will update the regulatory framework for novel foods, inclusive of cloned foods, and repeal the 1997 Novel Foods Regulation, which also copes with cloned foods.

On the other hand, the principle of substantial equivalence swiftly became a pillar of risk regulation for modern agricultural biotechnology and the benchmark standard against which the safety of biotech foods in the EU would be assessed[92], primarily through the Novel Food Regulation[93] .

Substantial equivalence is the scientific criterion by which the evaluation of novel foods is weighed when an applicant notifies the placing on the market to the national competent authority. If a novel food is not substantially equivalent to an existing food, the food must undergo an "initial" safety assessment by the competent authority of a Member State, and may then proceed to premarket authorization, as an authorization decision is required[94].

If the novel food is "substantially equivalent" to an existing food, it falls under the scope of the simplified procedure that exists under art. 3 (4). In this instance, applicants would simply have to notify the European Commission of the placing of the food on the market. No specific pre-market approval is required to put the novel food on the market.

Moreover, the labelling of novel foods under the scope of the 1997 Novel Foods Regulation is based on the concept of substantial equivalence. Article

[92] For more on Risk Regulation see E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing, 2010); J. Steele, *Risks and Legal Theory* (Oxford: Hart Publishing, 2004); and C.R. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press, 2005).

[93] The EU embraced the concept in the 1997 with *the Novel Food Regulation* (see art. 3(4).

[94] See e.g. N. Salmon, 'A European Perspective on the Precautionary Principle, Food Safety and the Free Trade Imperative of the WTO' (2002) 27 *E.L. Rev.* 138.

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8(1)(a) ensures the labelling of a novel food if this food is "no longer equivalent to an existing food". In sum, if a novel food is claimed substantially equivalent to an existing food, no specific labelling is required. They are submitted to general labelling prerequisites. However, substantial equivalence meaningfully narrows consumer choice by demanding no specific mandatory labelling and no traceability. It also brings into questions the safety of biotech products if they only undergo minimal premarket authorization.

The dynamic between substantial equivalence and the precautionary principle is problematic and it prevents the existence of an adequate and efficient regulatory environment for EU biotech foods regulation and undermines a comprehensive precautionary approach towards such foods and the EU food system in general. Moreover, at a general perspective, we can observe that not only the two concepts seem contradictory, but they underline the limits of a vision that continue to compare the "promotional" US model versus the "preventive" EU model, leaving the floor for further necessary studies on the impact of local variations in biotechnology policy and regulation responding to social concreate demands.

7. Going beyond the existing regulatory models. Concluding remarks on a sustainable approach

The previous pages have explained the main regulatory models and issues of modern agri-food biotechnologies focusing, in particular, on the European context and the current debate on green gene editing techniques. This was performed with the aim to explore whether these different regulatory models bring up interpretation and implementation challenges still fit for purpose or needs to be "reconsidered" at the light of current drawbacks. Implicitly, the features for a sustainable model were investigated.

The analysis has revealed that European current legislative approach tries to reach the balance of different rights and interests experimenting practically a mix of different models: practically meaning, both the precautionary principle and substantial equivalence interplay in the field, despite an apparent and formal shift from substantial equivalence, which on the contrary still plays a strategic role in both the regulation and the assessment of biotech foods (§ 6). This picture appears even

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more diversified when one examines the choices concretely opted for by the various Member States, in the light of their historical, social and political background (§ 3).

A preliminary conclusion confirmed what the doctrinal debate has underlined for long time: a regulation of the biotechnological process – mainly inspired to precaution - could lead to an assessment of the risks and potentialities of modern products unrelated to empirical data. It is necessary to assess the actual risks of the final product resulting from this process, thus avoiding that products similar in outcome are differentiated according to the characteristics of the technology, or that some technologies are not subject to consumer warnings despite being capable of accomplishing similar results to those subject to special legislation.

So far, from a legislative point of view, in future perspective, a case by case evaluation is widely recognized as an appropriate approach (see § 5), while the current model, as long as designed, could obstacle the proposition of a suitable model in line with current objectives.

Secondly, following the considerations developed in the paper, it underlined that a case-by-case determination of NGT products status through a pre-submission consultation will be more aligned with the current policy recommendations. The analysis did a step forward identifying some necessary ingredients for implementing a legislative model in line with current scientific development and social exigencies: a merely safety-based risk assessment may not be sufficient to promote sustainability and contribute to the objectives of the European Green Deal and especially the ones expressed in the "farm to fork" and biodiversity strategies; benefits contributing to sustainability would also need to be assessed as a suitable mechanism to accompany risk assessment may be required.

Policy instruments are needed to make the legislation more enduring, future-proof and uniformly applied. This is due to the fact that attempting to upgrade sustainability and guaranteeing safety would lead to overcome the choice between product-based or process-based exemption of NGT products, other than the coverage of NGT products under GMO legislation.

From a constructive point of view, thus, it would be worth considering the need for specific risk assessment criteria for NGTs as a starting point: it has been shown that the incorporated rigid risk-assessment guidance in EU legislation makes

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difficult to adjust it to scientific enhancement in order to be in line with social expectations. This consideration was the premise to find out what ingredients are outlining as suitable and necessary for a successful regulatory model promoting biotech foods worshipful of traditions and vice-versa: genome editing policies should consider not only risk assessment but also broader evaluations, including the societal value of genome-editing applications.

Ethical considerations have to incorporate scientific data and vice-versa, as ethical aspects of innovation in biotechnology should be viewed in light of the resulting organisms and intended uses rather than the technology used. In addition to safety, some countries already take additional factors into account in the final assessment/authorization of GMO, these also apply to NGT products and include ethical aspects, social acceptance, sustainable development, commercial and production impact, and perspective and benefits for indigenous people.

These will be some preliminary strategic approaches for designing an effective and socially desirable biotech regulation, coherent to balance the EU innovation objective and cultural food policy, compliant with the comprehensive EU responsible research and innovation policy[95]. A system designed in this way should more appropriately respond to the need of sustainability in a field, as the food one is, where sustainability goes beyond the environment and can entail seed and food security, safety, nutrition, competitiveness and social aspects.

Nevertheless, peculiarities of the genome editing technologies should be considered: if on the one hand, they require a "global" governance approach, on the

[95] Responsible Research and Innovation (RRI) is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation. It implies that societal actors (researchers, citizens, policy makers, business, third sector organizations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society. For more information see: https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation. Several studies seek to operationalize the definition of RRI. They individualize four dimensions of responsible innovation: anticipation (A), inclusion (I), reflexivity (R) and responsiveness (R): the so called AIRR framework is useful for discussing and responding to questions pertaining to the broader impacts of science and technology. Some scholars use this framework to set out a forward-looking governance framework for gene editing: see P. Macnaghten, M.G.L. Habets (n. 13).

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other hand it is difficult to take regulatory measures of worldwide scope that are efficient and respected by all States, so that these commit to ensuring compliance in their respective territories. It is not easy to identify criteria for the governance of genome-editing.

This requires reflection on the "forms" of uncertainties, on the rights and implied values, namely human dignity, solidarity, tradition, on the expectations set by this strategy, and on the limits and principles that should govern its implementation, as for example safety, effectiveness, efficiency, transparency, common good. As well as sustainability, also safety has to be framed in its broadest interpretation, including psychological, social and environmental spheres, as well as issues about who gets to decide what is safe enough, and by which processes[96]. Previous US analysis – reported in this paper - has already face this need: the 2016 US report on GMO mandatory labelling law was a proper past example of these exigences (see § 3).

What is reputed 'safe enough' is extremely context-dependent (compare §§ 4 and 5). What would be needed is the relevance of the entire decision issue to take safe, well reasoned responsible decisions in order to outweigh both the pros and the cons; indeed to consider not just the risks and costs but also the possible advantages, in the widest extent, and the distribution thereof.

The Green Deal has speeded up this switch and made the need for a more holistic, horizontal approach urgent, as it brings "all the tools and solutions under one roof" in order to cater to the quickly changing demands from society and evolving policy frameworks.

Anyway, whereas the Commission has determined a clear travel direction in food policy strategies, questions persist over how these aspirations will be implemented with a keen eye to social context peculiarities, such as for example the identification of the precise meaningful factors that can "measure" if the regulatory choice is suitable to balance the chosen model with local adaptations.

Taking these peculiarities into account in the revision of the regulatory model would help consumers to place greater trust in the legislator's pragmatic decisions to

[96] This is also remarked by the EGE Opinion (n. 42).

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guide them towards solutions that are increasingly compatible with the reasons for protecting health in a comprehensive way, namely *One Health*[97].

[97] For a detailed and clear explanation of the One Health concept and its impact on food law see D. Cerini, 'Sicurezza degli alimenti tra sostenibilità, benessere animale e gestione assicurativa dei rischi', M. Torsello (ed.), forthcoming.

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A proactive GDPR-compliant solution for fostering medical scientific research as a secondary use of personal health data

Giorgia Bincoletto and Paolo Guarda*

Abstract

The secondary processing of personal health data for scientific research in the medical field is fundamental for fostering innovation and growing knowledge that improves individual and public health. Personal health data that are primarily processed for healthcare purposes by healthcare providers may be secondarily used by researchers for scientific purposes. However, the data controller shall assess the applicable grounds and conditions and then comply with the data protection framework to safeguard fundamental rights and freedoms. In this paper we analyse the legal requirements laid down on these aspects by the General Data Protection Regulation at the European Union level, which harmonises the general rules, and by two national implementations at the Member State level, Italy and France, which further regulate with specific conditions. After this comparative investigation, we propose a proactive, legal-technical e-health solution that complies with the rules and principles of the legal frameworks and empowers the individual's control over personal health data while promoting medical research. To this end, the data protection by design concept plays a central role, and an interdisciplinary approach is fundamental in combining legal and technical perspectives.

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Table of Contents

Keywords

Health Data - Scientific Research - Personal Data - GDPR - Data protection by design

1. Introduction

Scientific research represents an unavoidable prerequisite to ensure the development of knowledge in multiple fields. It is rooted at a constitutional level that justifies the relevance of the interests it supports, also in a perspective of balance with other rights and principles recognised and protected by legal systems[1]. Whilst science is conducted for the benefit of mankind, individuals' and public interests coexist in modern societies.

Scientific research is indispensable for the progress of the healthcare sector[2]. Medical research responds both to the need to achieve a high level of health protection and provision of care and to the opportunity to foster innovation and grow knowledge. Research studies can be prospective or retrospective and require data. Frequently, these projects use personal data. In the health sector the relationship between individual and collective interests is emphasized: the processing of data relating to the patient's health

[1] The Charter of Fundamental Rights of the European Union specifies that scientific research shall be free of constraints (Art. 13). In the Italian Constitution, for instance, Article 33 establishes the principle of freedom of science, and Article 9 proactively obliges the Republic to promote "the development of culture and scientific and technical research".

[2] According to the World Health Organisation (WHO), high-quality health research is indispensable for many reasons, including resolving global threats, developing vaccines and medicines, and generally for the attainment of the highest level of health. *See* the information provided at *https://www.who.int/health-topics/research/#tab=tab_2*.

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status becomes, indeed, useful to the natural person in order to take care of the disease that afflicts her, but at the same time, it is also essential in contributing to scientific progress, meaning developing and evaluating strategies, services, solutions and policies.

The right to health of the individual, the right to protection of personal data concerning health, public health and the underlying public interests are all protected by modern legal frameworks[3]. This scenario is certainly characterized by a high level of complexity, and it is necessary to achieve a correct balance of the rights involved[4]. The obvious benefit in terms of individual care must, in fact, be balanced with the more general need to protect and enhance public health. Some criteria aimed at determining the correct point of contact between these needs should be identified.

From an ethical point of view, the processing of information in the health sector may be configured as a real right and duty of the individual to make the data relating to her health available to healthcare providers, including researchers[5]. The advantage will not only be for the natural person, who will benefit from health services provided in the light of an information framework as complete and advanced as possible, but for the entire community who will benefit from increased opportunities in terms of public (health) safety and scientific progress[6]. At the same time, privacy and confidentiality of research subjects

[3] At the EU level, the right to health, meaning the right of access to preventive healthcare and the right to benefit from medical treatment, is provided by Article 25 of the Charter of Fundamental Rights of the European Union. The definition of "public health" is established by Article 3 of Regulation (EC) No 1338/2008.

[4] *See* F. Di Ciommo, 'Il trattamento dei dati sanitari tra interessi individuali e collettivi' (2002) 2 *Danno e Resp.*, pp. 121-134. On balancing rights at the constitutional level *see ex multis* A. von Bogdandy and B. Jürgen, *Principles of European Constitutional law* (Hart Publishing, 2020); R. Alexy, *A theory of constitutional rights* (Oxford University Press, 2010).

[5] *See* M. Mostert *et al.*, 'From Privacy to Data Protection in the EU: Implications for Big Data Health Research' (2017) 25 *European Journal of Health Law* 1, p. 44, which refers to an "*ethical and scientific imperative*" of the individual to share personal data to be used for research activities; *see* also I.G. Cohen, 'Is There a Duty to Share Healthcare Data?' in I. Glenn Cohen and others (eds.), *Big Data, Health Law, and Bioethics* (Cambridge University Press, 2018). In the Communication on the European Data Strategy of 2020, the European Commission uses the term "data altruism", meaning the possibility of making "*easier for individuals to allow the use of the data they generate for the public good, if they wish to do so*". *See* 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", 2020, p. 13. This approach of "data altruism" is even contained in the Proposal for a Regulation of the European Parliament of the Council on European data governance, COM/2020/767 final, which will improve the European Health Data Space.

[6] For further details with reference to scientific research and personal data protection issues, *see* R. Ducato, 'Data protection, scientific research and the role of information' (2020) 37 Computer Law and Security Review, available at *https://www.sciencedirect.com/science/article/pii/S0267364920300170*; D. Amram, 'Building

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should always be guaranteed[7], as provided by the Helsinki Declaration[8] and the Oviedo Convention[9].

From a legal point of view, the processing of personal data for research is bound by European Union (EU) and national data protection requirements. Actually, many rules have been introduced to safeguard natural persons with regard to the processing of their health data. The data protection field provides conditions that limit the processing of information for scientific purposes and determine the lawful point of contact between the interests mentioned[10]. In fact, the perspective of availability of patients' data for scientific research is counterbalanced by obligations upon those who provide healthcare professionally and are also interested in medical scientific research activities. Healthcare providers should process the data that are necessary to provide the healthcare service to the individual and useful for managing high-quality health systems. Suitable measures and guarantees should be adopted to protect personal health data. In this context, where data are first collected for healthcare provision (primary purpose is healthcare), it is often not easy to identify later the grounds and conditions for lawfully processing personal data stored in Electronic Health Record systems (EHRs) or in other repositories for scientific purposes (re-use of data for the secondary research purpose)[11].

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up the "Accountable Ulysses" model. The impact of GDPR and national implementations, ethics, and health-data research: Comparative remarks' (2020) 37 Computer Law & Security Review, available at *https://www.sciencedirect.com/science/article/pii/S0267364920300182*.

[7] In this sense following codes of conduct and best practices is very helpful. A Code of Conduct for health research is currently under development in the EU framework by BBMRI-ERIC, a European research infrastructure for biobanking, which is taking into account pivotal issues like consent of data subjects. *See* updated information on this initiative at *http://code-of-conduct-for-health-research.eu/*.

[8] According to Article 24 of the WMA Declaration of Helsinki - Ethical Principles for Medical Research, "every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information".

[9] The Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) includes Article 10 on "private life and right to information".

[10] According to the Council of Europe, "scientific research purpose" refers to a processing that is aimed "at providing researchers with information contributing to an understanding of phenomena in varied scientific fields (epidemiology, psychology, economics, sociology, linguistics, political science, criminology, etc.) with a view to establishing permanent principles, laws of behaviour or patterns of causality which transcend all the individuals to whom they apply". *See* Council of Europe, "Explanatory Report to the Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data", 2018, p. 9.

[11] The extensive and recent report TIPIK Legal, "Report on the implementation of specific provisions of Regulation (EU) 2016/679", European Commission, 2021, p. 70, in the section on "secondary use of health data for scientific or historical research" states: "*The literature shows that identifying the correct legal bases for use in*

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This article focuses on issues relating to the determination of the legal basis and conditions that enable the secondary processing of personal health data for scientific purposes in the medical field under the EU law on data protection. A correct interpretation of the legal ground is crucial to set up the research since it impacts on the applicable rights of the data subjects and other conditions under which the researchers should work[12]. The analysis does not examine the processing situation where personal data are directly collected for research purposes, but rather its focus is on further processing of these data for medical research. Although the General Data Protection Regulation has harmonised the rules governing data processing, it has left room for further regulation on personal health data at the Member State level.

After a comparative law approach that highlights the differences between two Member States' legislation implementing the EU Regulation - Italy and France - the research proposes a proactive e-health solution that complies with the rules and principles of the General Data Protection Regulation and empowers the individual's control over personal health data while promoting medical research. So, the research uses both legal comparison and the interdisciplinary method of "law and technology".

The paper is organised as follows. After this introduction, the second paragraph will be dedicated to a brief overview of the general data protection framework that governs scientific research activity at the European level with particular attention to health data. Then the third and fourth paragraphs will analyse two national implementations of the EU data protection rules relating to research in the medical field: the Italian and the French legal systems. The fifth paragraph will be aimed at providing the conceptual foundations of a cardinal principle of the new European order, "data protection by design", that will be applied to a specific operating scenario in order to propose a proactive legal-technical solution based on an interdisciplinary approach. In the conclusive remarks we will try to summarise the juridical-conceptual approaches to the issue and propose possible future evolutions.

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the context of research is in practice difficult. A major source of uncertainty for industry is the appropriate legal basis for processing data in the absence of explicit consent, and understanding what activities reasonably fall under the various exemptions provided by the GDPR. (...) It has also been highlighted that there is uncertainty to which extent existing national laws apply. (...) It is also worth keeping in mind some processing activities may fall under different legal bases simultaneously – particularly if an extremely narrow scope is assigned to each basis".

[12] The same remark is stressed by G. Schneider and G. Comandé, 'Differential Data Protection Regimes in Data-Driven Research: Why the GDPR Is More Research-Friendly Than You Think' (2021) *German law Journal* 2021, available at SSRN: *https://ssrn.com/abstract=3897258*, pp. 9-10.

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2. Scientific research and personal health data in the EU framework: selected issues

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation; hereinafter: "GDPR")[13] confirms European legislators' preference for processing for research purposes, whether "secondary" or carried out for a primary purpose, following the approach of the former Directive 95/46/EC[14]. A special and privileged regime on data processing related to research activities has been provided in the GDPR.

Starting from the definition of the material scope, scientific research is very broadly defined. Recital 159 lists some examples such as: "*technological development and demonstration, fundamental research, applied research and privately funded research* [...]. *Scientific research purposes should also include studies conducted in the public interest in the area of public health*"; furthermore, "*if the result of scientific research in particular in the health context gives reason for further measures in the interest of the data subject, the general rules of this Regulation should apply in view of those measures*". Hence, research can be promoted for both individual and public interests.

To enhance scientific research, the GDPR provides an exception to the cornerstone purpose limitation principle. Article 5, par. 1, letter b), states: "*further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation')*"[15]. A scientific research purpose is *a priori* considered compatible.

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[13] On the GDPR *see ex multis* C. Kuner et al, *The EU General Data Protection Regulation (GDPR): A Commentary* (Oxford University Press, 2020); B. Van der Sloot, *The General Data Protection Regulation in Plain Language* (Amsterdam University Press, 2020); V. Cuffaro, R. D'Orazio, and V. Ricciuto, *I dati personali nel diritto europeo* (G. Giappichelli Editore, 2019); P. Voigt and A. Von dem Bussche, *The EU General Data Protection Regulation (GDPR). A Practical Guide* (Springer International Publishing, 2017); G. Finocchiaro, *Il nuovo Regolamento europeo sulla privacy e sulla protezione dei dati personali* (Zanichelli, 2017).

[14] *See* G. Chassang, 'The impact of the EU general data protection regulation on scientific research' (2017) 11 Ecancermedicalscience, p. 709, available at *https://www.ncbi. nlm.nih.gov/pmc/Articles/PMC5243137/*); M.L. Manis, 'The processing of personal data in the context of scientific research. The new regime under the EU-GDPR' (2017) 3 BioLaw Journal, pp. 325-354.

[15] *See* C. De Terwangne, 'Chapter II Principles (Articles 5-11), Article 5. Principle relating to processing of personal data', in Kuner et. al (ed.), *The EU General Data Protection Regulation (GDPR): A Commentary* (Oxford University Press, 2020), pp. 309-397. According to the purpose limitation principle, personal data shall be collected for specified, explicit and legitimate purposes. Personal data shall not be processed for incompatible purposes. According to this chapter, the concept of "compatible" is problematic. Some

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Moreover, in Article 14, par. 5, letter b), a wide derogation is stated with reference to the informational obligation in the case of indirect collection of personal data; there is a series of options: disproportionate effort, impossibility or serious prejudice for the purpose of research, etc.

Finally, Article 89, the pivotal regulatory provision with reference to scientific research, allows a series of possible exceptions to the rights referred to in Articles 15 ff GDPR[16], on the assumption that adequate guarantees are adopted for to protect the rights and freedoms of the data subject. In this regard, the data controller may comply with the aforementioned obligation, in particular in order to guarantee compliance with the principle of data minimisation, by means of "pseudonymisation" techniques[17]. In addition to technical and organisational measures, research should follow "*recognised ethical standards*" as recommended by Recital 33 GDPR.

Turning now to the particular type of data generally processed in the medical scientific context, we define "data concerning health" those "*personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status*" (Article 4, pt. 15, GDPR)[18]. They are included in the list of special

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criteria are provided by Article 6, par. 4, GDPR, but the data controller should evaluate the extent of the purpose on a case-by-case basis.

[16] *See* further on Article 89 GDPR, G. Comandé, 'Ricerca in sanità e data protection un puzzle... risolvibile' (2019) 1 Rivista Italiana di Medicina Legale (e del Diritto in campo sanitario), pp. 189–207. On the implementation of Article 89 in Member States' legislation *see* TIPIK Legal, "Report on the implementation of specific provisions of Regulation (EU) 2016/679", *op. cit.*, pp. 29–39; DG Health and Food Security, "Assessment of the EU Member States' rules on health data in the light of the GDPR", European Commission, 2021, pp. 60-81.

[17] Article 4, no. 5, GDPR: "'*pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person*". *See* further on pseudonymisation ENISA, European Union Agency for Network & Information Security, 'Recommendations on shaping technology according to GDPR provision. An overview on data pseudonymisation', 2018; L. Tosoni, 'Chapter I General principles (Articles 1-4). Article 4(5). Pseudonymisation', in Kuner et. al (ed.), *The EU General Data Protection Regulation (GDPR): A Commentary* (Oxford University Press, 2020).

[18] *See* Lee A. Bygrave and L. Tosoni, 'Chapter I General principles (Articles 1-4). Article 4(15). Data concerning health', in Kuner et. al (ed.), *The EU General Data Protection Regulation (GDPR): A Commentary*. cit., pp. 215–224; T. Mulder, 'The Protection of Data Concerning Health in Europe' (2019) 5 Eur. Data Prot. L. Rev., pp. 209–220; M. Granieri, 'Il trattamento di categorie particolari di dati personali nel reg. UE 2016/679' (2017) 1 Nuove leggi civ. comm., 165-190; P. Guarda, 'I dati sanitari', in Cuffaro et al (ed.), *I dati personali nel diritto europeo* (G. Giappichelli Editore, 2019), pp. 591-626; G. Schneider, 'Disentangling Health Data Networks: a Critical Analysis of Art. 9.2 and Art. 89 GDPR' (2019) 9 International Data Privacy Law 4, pp. 253-271. An interesting in-depth analysis on "quasi-health data" defined as "*information that indirectly reveals data about health status*" in G. Malgieri and G. Comandè, 'Sensitive-by-distance: quasi-health data in the

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categories of personal data referred to in Article 9 GDPR and, therefore, subject to the general prohibition of processing sanctioned in the first paragraph[19]. There are, however, some exceptions to this prohibition, which can be divided into three groups[20]: 1) the consent[21] of the data subject pursuant to Article 9, par. 2, letter a) and, closely related to it, the need to protect a vital interest of the data subject (letter c)), as well as the manifest publicity of personal data (letter e)); 2) processing needed for reasons of substantial public interest (letter g)), for the purposes of preventive or occupational medicine, medical diagnosis, provision of health or social care or treatment or management of health or social care and systems and services referred to in letter h) (hereinafter: "healthcare exception"), and for reasons of public interest in the field of public health pursuant to letter i); 3) the processing necessary for scientific or historical research purposes or for statistical purposes pursuant to Article 9, par. 2, letter j) (hereinafter: "research exception").

This discipline is complementary to the general requirements for lawful data processing pursuant to Article 6 GDPR (consent, pursuant to par. 1, letter a); execution of a task of public interest, pursuant to par. 1, letter e); legitimate interest, pursuant to paragraph 1, letter f)). The existence of a law of a general nature, then, becomes the prerequisite for processing particular categories of data.

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algorithmic era, in Information & Communications Technology Law' (2017) 26 Information & Communications Technology Law 3, pp. 229–249.

[19] For further details on special categories of data, *see* L. Georgieva and C. Kuner, 'Art.9 Processing of special categories of personal data', in Kuner et al. (ed.), *The EU General Data Protection Regulation (GDPR). A Commentary*, cit., pp. 365-384.

[20] *See* G. Schneider, 'Health Data Pools under European Policy and Data Protection Law: Research as a New Efficiency Defence' (2020) 11 JIPITEC, p. 61. *See* further G. Schneider and G. Comandé, 'Differential Data Protection Regimes in Data-Driven Research: Why the GDPR Is More Research-Friendly Than You Think', cit., pp. 11-18.

[21] Consent has been defined as a "freely given, specific, informed and unambiguous indication" of the will of the data subject. See Article 2, par. 11, GDPR. Recital 33 specifies that "*It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose*". It can then be argued that a flexibility in defining the purpose of the scientific study can be found in the words of the GDPR. On this matter see also EDPB, "Guidelines 5/2020 on consent under Regulation 2016/679", 2020, available at *https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf*. The Authority highlights that in the case of processing of a particular category of data, this flexibility should be subject to a stricter interpretation than in other cases. Then, a data processing with medical research purposes that processes personal health data the purpose of research should be narrowed down as much as possible.

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Some critical profiles of "failed harmonisation" may emerge from the provisions of Article 9, par. 4, GDPR which allows Member States to decide whether or not to maintain the legal bases provided by the EU regulation or introduce additional conditions and limitations, with regard to the processing of particularly sensitive data, such as biometric, genetic, or health-related data[22]. Derogations and different national regimes may create barriers to research activities.

Lastly, the "Preliminary opinion on data protection and scientific research", adopted on 6 January 2020 by the European Data Protection Board[23] and the "EDPB Document on response to the request from the European Commission for clarification on the consistent application of the GDPR, focusing on health research", of 2 February 2021[24] complete the main regulatory framework. In the first document the EDPB reviews the ethical standards applicable to scientific research and analyses selected issues of the data protection framework. The right to information and the nature of informed consent play pivotal roles. The authority specifies that the presumption of compatibility requires a careful analysis by the controller, and it even requires the implementation of the safeguards of Article 89, such as a DPIA[25]. In fact, purpose specification (and compatibility) is a different requirement from the lawfulness of the data processing. The second recent document highlights the existence of legal grounds other than the explicit consent of the data subjects since this basis may be inappropriate in research studies where there is an imbalance of power between the controller and the individuals. Moreover, the EDPB clarifies that when personal health data are collected for a primary purpose based on the "healthcare exception", and the controller relies on the presumption of compatibility for a secondary

[22] According to Article 168(7) of the Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, actually, Member States have competence on the protection and improvement of human health, while the EU on carrying out actions to support, coordinate or supplement national actions. On this competence *see* G. Di Federico and S. Negri, *Unione Europea e Salute. Principi, azioni, diritti e sicurezza* (Cedam, Wolters Kluwer 2020); M. Flear, *Governing Public Health: EU Law, Regulation and Biopolitics* (Bloomsbury Publishing, 2015); T. K. Hervey and J. V. McHale, *European Union health law* (Cambridge University Press 2015); S.L. Greer *et al*, 'Everything you always wanted to know about European Union health policies but were afraid to ask', World Health Organization, Regional Office for Europe, 2014.

[23] The opinion is available at *https://edps.europa.eu/data-protection/our-work/publications/opinions/preliminary-opinion-data-protection-and-scientific_en*.

[24] Available at *https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf*. This document promises the publication in 2021 of specific "Guidelines on processing personal data for scientific research purposes" by the EDPB.

[25] *See* EDPB, "Preliminary Opinion on data protection and scientific research", p. 22, and p. 24 on examples of safeguards.

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scientific research purpose, the conditions and safeguards of Article 9 still apply, meaning an exception based on EU or Member State law must be found.

EU law does not define the safeguards under Article 9, par. 2, letter j), meaning different conditions may be established by Member States' law for scientific research in the medical field according to this provision and to Articles 9, par. 4, and 89 GDPR[26]. The EDPB reported that Member States' laws "*generally require prior informed consent from the participant in a research project for the processing of health data*" unless exceptional situations apply[27]. It should be stressed here that this consent is different from informed consent as a human participant in a scientific research study, which is also an ethical requirement.

In the following paragraphs, we will describe two examples of national implementation of the EU regulation, taking into account the Italian and the French legal systems that introduced specific rules on scientific research pursuant to the necessary adjustments to the GDPR and the possibility of derogation. A brief comparison between the two different approaches is provided at the end of section 4 that also highlights some criticalities and gaps left open by the EU and the two Member States' frameworks.

3. The Italian implementation

Within the Italian legal system, a framework dedicated to the processing of personal data for research purposes had already been provided in Title VII "Processing for historical, statistical and scientific purposes" of the former d.lgs. 30 June 2003, no. 196 "Personal Data Protection Code" (hereinafter: "IDPC"): in particular, on scientific research, Chapter III, Articles 104-110. The legislative decree 10 August 2018, no. 101[28] - the National

[26] On Member States' law *see* TIPIK Legal, "Report on the implementation of specific provisions of Regulation (EU) 2016/679", *op. cit.*, pp. 7–15; DG Health and Food Security, "Assessment of the EU Member States' rules on health data in the light of the GDPR", *op. cit.*, pp. 57–81.

[27] *See* EDPB, "Preliminary Opinion on data protection and scientific research", p. 14. Informed consent is the legal basis for clinical trials according to Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014. In particular, *see* Articles 28. On the interplay between this Regulation and the GDPR *see* EDPB, "Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR)", European Commission, 2019.

[28] Legislative Decree No. 101 of 10 August 2018 "Disposizioni per l'adeguamento della normativa nazionale alle disposizioni del regolamento (UE) 2016/679 del Parlamento europeo e del Consiglio, del 27 aprile 2016, relativo alla protezione delle persone fisiche con riguardo al trattamento dei dati personali, nonché alla libera circolazione di tali dati e che abroga la direttiva 95/46/CE (regolamento generale sulla protezione dei dati)".

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adaptation of the IDPC to the GDPR - has substantially preserved the previous provisions, but it has changed some terminology, regulatory references, and added an ethical requirement.

Article 110 IDPC represents here the pivotal provision with regard to research in the medical, biomedical and epidemiological fields. As mentioned, it mainly remained unchanged, but Italian legislators added some targeted adjustments to the GDPR (Articles 9 and 89 upfront) by highlighting the importance of the Data Protection Impact Assessment (DPIA) as regulated by Articles 35 and 36 GDPR. Research in the medical field is to be considered a *species* of the broader *genus* of scientific research. It could be declined in terms of "biomedical research" and "epidemiological research". On the one hand, the first category of research refers to an interdisciplinary approach that applies the principles of biology and natural sciences to clinical practice; on the other hand, the second one is the science that studies the phenomenon of the onset of diseases in the population, with particular regard to the study of the conditions and factors that determine them.

Before analysing the conditions of Article 110 IDPC, it is necessary to take into account the guidelines and requirements of the Italian Data Protection Authority (Italian DPA) specifically issued for scientific research. The Italian DPA, by means of the "Provisions identifying the requirements contained in the General Authorizations nos. 1/2016, 3/2016, 6/2016, 8/2016 and 9/2016 which are compatible with the GDPR and Legislative Decree no. 101/2018" specified the requirements contained in the general authorizations for data processing adopted in 2016 that are still compatible with the new European regulation and with the recent reform of the IDPC. In particular, Annex 1 of these Provisions at point 5 provides "Requirements relating to the processing of personal data carried out for scientific research purposes (hereinafter: "Scientific research requirements"), which concern processing performed by: a) universities, other research bodies or institutes and scientific societies, as well as researchers working in the field of those universities, organizations, research institutes and the members of those scientific societies; b) health professionals and health organizations; c) natural or legal persons, entities, associations and private bodies, as well as subjects specifically responsible for processing such as designated data processors (researchers, monitors, expert commissions, contract research organizations, analysis laboratories, etc.) (Art. 2-quaterdecies IDPC, and 28 GDPR) (point 5.1). These requirements concern the processing of personal data for medical, biomedical and epidemiological research purposes carried out when: the processing is necessary for studies conducted with data previously collected for healthcare purposes, meaning under the "healthcare exception"; the processing is necessary for the execution of previous research

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projects or obtained from biological samples previously taken for health protection purposes or for the execution of previous research projects; and, the processing is necessary for studies conducted with data referring to people who, due to the seriousness of their clinical state, are unable to understand the information provided in the privacy policy and therefore validly given consent is not possible (point 5.2). Furthermore, Annex 1 Point 4 provides "Requirements relating to the processing of genetic data"[29].

Beyond the Scientific research requirements, it is also necessary to take into account the "Deontological regulation for processing for statistical or scientific research purposes published pursuant to Art. 20, paragraph 4, of legislative decree 10 August 2018, no. 101 - 19 December 2018" (hereinafter "Deontological Regulation") where the research activity does not concern "*processing for statistical and scientific purposes connected with health protection activities carried out by health professionals or health organizations, or with comparable activities in terms of significant personalized impact on the interested party, which remain governed by the relevant provisions*" (Art. 2, par. 2)[30].

So, taking into account the combination of all the requirements provided for scientific research activity in the medical field, it can be argued that consent represents a basic condition for data processing. In this sense, the Scientific Research Requirements in point 5.3, paragraph 2, ("Consent") establish that "*The obligation to collect consent to the processing of data of data subjects included in the research remains in all cases in which, during the study, it is possible to provide them with adequate information and, in particular, where they go to the treatment center, also for check-ups*". The same principle can be deduced by reading Articles 7, par. 2, and 8, par. 4, if applicable, of the Deontological Rules. Hence, the data controller should provide adequate information and collect consent of the data subjects involved in the scientific projects.

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[29] For further details with reference to genetic data and scientific research, *see* K. Pormeister, 'Genetic data and the research exemption: is the GDPR going too far' (2017) 7 IDPL, pp. 137-146; P. Quinn and L. Quinn, 'Big genetic data and its big data protection challenges' (2018) 34 Computer Law & Security Review, pp. 1000-1018; M. Shabani and P. Borry, 'Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation' (2018) 26 European Journal of Human Genetics, pp. 149-156; J. Kaye *et al.*, 'Dynamic consent: a patient interface for twenty-first century research networks' (2015) 23 European Journal of Human Genetics 2, pp. 141-146; J. H. Gerards, 'General Issues concerning Genetic Information', in Gerards *et al* (ed.), *Genetic Discrimination and Genetic Privacy in a Comparative Perspective* (Oxford University Press, 2005), p. 5.

[30] Art. 8 of the Deontological Regulation is dedicated to medical, biomedical and epidemiological research and states that research activity is carried out "*in compliance with the relevant international and community guidelines and provisions, such as the Convention on human rights and biomedicine of 4 April 1997, ratified by law 28 March 2001, no. 145, the Recommendation of the Council of Europe R (97) 5 adopted on February 13, 1997 on the protection of health data and the Declaration of Helsinki of the World Medical Association on principles for research involving human subjects*".

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However, the first paragraph of Article 110, starting from the assumption that such a condition is required, defines some cases and situations in which consent is not necessary.

First of all, consent is not needed for data processing with scientific research purposes in the medical, biomedical and epidemiological fields that is carried out on the basis of a legal or regulatory provision at the national level, or at the European Union level under Article 9, par. 2, letter j) GDPR. Then Article 110 expressly mentions, as a paradigmatic example, the research that is part of a program pursuant to Article 12-bis of Legislative Decree no. 502/1992 ("Reorganization of the health legislation, pursuant to Article 1 of Law no. 421 of 23 October 1992")[31]. This provision, first of all, governs the "National Health Plan" (paragraph 2), which is envisaged with reference to the needs of the National Health Service and takes into account the objectives set out in the National Research Program. This Plan is regularly put in place by the Ministry of Health, after consulting the National Commission for Health Research, in agreement with the Permanent Conference for relations between the State, the Regions and the autonomous Provinces of Trento and Bolzano (paragraph 3). The Program aims to identify the objectives that are national priorities to improve the state of health of the person (paragraph 4) and it also promotes experimentation and methods of operation, management and organization of healthcare services, as well as clinical practices and assistance. Under the plan, the research activity can be classified as a "current" research or a "finalized" research (paragraphs 5 and 6). The current research is implemented through the institutional projects of research organisations within the guidelines of the national program, as approved by the Ministry of Health; the finalized research, instead, contributes to addressing the biomedical and health objectives of the National Health Plan.

Preliminary to a data processing with a research purpose under this first exception is that a DPIA is drafted and made public pursuant to Articles 35 and 36 GDPR. Therefore, this processing situation only requires a compliant risk assessment. Only if the condition of Article 36, par. 1, GDPR applies, meaning the processing would result in a high risk in the absence of mitigating measures, the data controller shall consult the DPA.

The other case of exemption enshrined in the second part of the first paragraph of Article 110 IDPC applies to data processing with a research purpose where "*for particular reasons, informing the data subjects is impossible or involves a disproportionate effort, or risks making it*

[31] *See* G. Raimondi, 'Ricerca medica, biomedica ed epidemiologica. Commento all'Art. 110', in Aa.Vv., *Codice della Privacy. Commento al Decreto Legislativo 30 giugno 2003, n. 196 aggiornato con le più recenti modifiche legislative*, Tomo I (Giuffrè, 2004), p. 1416.

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impossible or seriously jeopardizing the achievement of the purposes of the research". In addition to this provision, point 5.3 of the Scientific Research Requirements specifies that in such a processing activity the data controller shall document the existence of the particular reasons mentioned in Article 110 directly in the research project (in line with the general principle of accountability). Hence, this subject shall define a reason, considered wholly particular or exceptional, for which informing the data subjects is impossible or involves a disproportionate effort, or risks making it impossible or seriously jeopardizing the achievement of the research objectives. If it applies, the information (and consent) can be avoided. In particular, the following options have been identified by the Italian DPA:

A. "ethical reasons", linked to the fact that the data subject ignores her condition. This situation applies when the information on data processing may involve the disclosure of information concerning the conduct of the study whose knowledge may cause material or psychological damage to the data subject herself[32];

B. "organisational impossibility reasons", where the failure to consider the data referring to the estimated number of data subjects, who cannot be contacted to be informed, compared to the total number of subjects intended to be involved in the research, would produce significant consequences for the terms of alteration of the relative results[33];

C. "health reasons", attributable to the seriousness of the clinical state in which the data subject is, due to which she is unable to understand the information provided in the privacy policy and provide valid consent. In addition, the study should aim to improve the same clinical state of the data subject, and the controller should provide proof of the impossibility of achieving the scientific purpose through a processing of data referring to persons who are able to understand the information and provide valid consent or by the use of other research methodologies.

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[32] See for example epidemiological studies on the distribution of a factor that predicts or can predict the development of a morbid state for which there is no treatment.

[33] In this regard, it is necessary to consider in particular the inclusion criteria provided by the study, the enrolment methods, the statistical number of the chosen sample, as well as the period of time elapsed from the moment in which the data referring to the interested parties were originally collected (see for example the cases in which the study concerns individuals with pathologies with a high incidence of mortality or in the terminal phase of the disease or in old age and in serious health conditions); finally, in this context it is also necessary to include the processing of the data of those who are deceased or not contactable at the time of enrolment in the study, after every reasonable effort has been made to contact them, including by verifying whether they are alive, consulting the data reported in the clinical documentation, contacting any telephone numbers provided, as well as acquiring contact data at the registry office of the assisted persons or of the resident population.

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As regards this second exception, a prerequisite for data processing with a research purpose is drafting a detailed research program with a sufficiently explicit research purpose and obtaining a reasoned favourable opinion from the competent ethics committee at the local level. Moreover, a DPIA must be drawn up, which must necessarily be submitted for consultation to the Italian DPA pursuant to Article 36 GDPR[34]. Here, the data controller shall consult irrespective of the risks involved and the measures implemented. This requirement does not define the request for consultation as a "request for authorisation". Therefore, the consequences of the silence of the Italian DPA on a specific request are open to interpretation. It might be argued that this silence may not interrupt the beginning of a lawful data processing since the provision should have made explicit the need for prior authorisation as established by Article 110-bis IDPC.

Whether the first or second exception applies, Article 110, par. 2, IDPC provides some exceptions to the application of the right of rectification under Article 16 GDPR, in light of the requirements (and possibility of derogations) of Article 89, par. 2 GDPR. If the data subject exercises the right to obtain without undue delay the rectification of inaccurate personal data or the right to have incomplete personal data completed, the activity of rectification and integration must be carried out without modifying the data by annotating a statement as long as the result of these operations does not produce significant effects on the research results[35].

For the sake of completeness, it is worth noting that Article 110-bis IDPC establishes that the Italian DPA may authorize further processing of personal data, including those of the special processing referred to in Article 9 of GDPR, for scientific research or statistical purposes by third parties. These third parties mainly carry out these activities when, for particular reasons, informing the interested parties is impossible or involves a disproportionate effort or risks, making impossible or seriously jeopardizing the achievement of the purposes of the research, provided that appropriate measures are taken to protect the rights, freedoms and legitimate interests of the data subject, in accordance

[34] The framework confirms the provisions at the European level regarding clinical trials of medicines for human use (*see* EU Regulation no. 536/2014) and the indications of the National Bioethics Committee (*see* National Bioethics Committee, pediatric biobanks 11 April 2014, 12). For further details, *see* C. Casonato and M. Tomasi, 'Diritti e ricerca biomedica: una proposta verso nuove conoscenze' (2019) 1 BioLaw Journal – Rivista di BioDiritto, pp. 343-358.

[35] The Deontological Regulations take up this provision and Art. 12 ("Exercise of data subject rights) provides that: "*If, in the event of the exercise of the rights referred to in Art. 15 and ff. of the Regulations, changes are necessary to the data concerning the data subject, data controller shall note, in the appropriate spaces or registers, the changes requested by the data subject, without changing the data originally entered in the archive*".

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with Article 89 GDPR, including preventive forms of data minimisation and anonymisation.

As a result, such a processing situation is domain-limited since only particular data controllers that mainly carry out research activities can benefit from its application (Art. 110-bis, par. 1, IDPC); furthermore, they do not process personal data for a scientific purpose that is instrumental to healthcare services, meaning they are not private or public institutions of hospitalisation and care (Art. 110-bis, par. 4, IDPC). Specific safeguarding measures and a prior consultation with the Italian DPA are binding. Without an authorisation, which also defines the necessary safeguarding measures, starting the processing is unlawful (Art. 110-bis, par. 2, IDPC). It can be argued that the Italian legislator has implemented Article 16, par. 5, GDPR, which allows Member State law to require controllers to consult in advance in relation to processing. However, according to Article 110-bis, par. 3, IDPC the Italian DPA may issue general authorisations that specify conditions and measures for third parties who mainly carry out research and statistical activities.

Looking at a situation where personal health data are first collected and processed under the "healthcare exception" provision, and the data controller seeks to use these data for a secondary medical research purpose, without anonymising them, meaning carrying out a prospective or retrospective study, it can be argued that the basic condition of explicit consent applies, unless one of the situations of Article 110 IDPC is applicable (regulatory basis or particular proven reasons). In any case, it is highly likely that a DPIA will be required as an *ex ante* tool for compliance.

4. The French implementation

The French legal system provides rules dedicated to the processing of personal data for research purposes in the medical field and conditions and limitations for the data processing of personal health data in Law no. 78-17 of 6 January 1978 on information technology, data files and civil liberties (hereinafter: LIL)[36] and Law no. 2018-493 of 20 June 2018 on the protection of personal data[37], which adapted the national regulation to the GDPR[38].

[36] Loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés.

[37] Loi n° 2018-493 du 20 juin 2018 relative à la protection des données personnelles.

[38] On the French implementation of the GDPR *see* O. Tambou, 'GDPR Implementation Series - France: The French Approach to the GDPR Implementation' (2018) 4 Eur. Data Prot. L. Rev. 1, pp. 88-94.

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This framework defines detailed rules for data processing with scientific purposes: it requires the processing to be subject to baseline and standard rules laid down by the French Data Protection Authority, the Commission nationale de l'informatique et des libertés (hereinafter: CNIL)[39].

First of all, Article 4 of the LIL mentions the research exception to the purpose limitation principle, and specifies that a research purpose is not incompatible with the primary purpose as long as the processing is carried out in compliance with the GDPR, and is not used to make decisions with regards to data subjects. So, the compatibility of research is confirmed at the national level following Art. 5, par. 1, letter b) GDPR.

Secondly, Article 8, par. 1, point 2(c) of the LIL specifically refers to Article 9, par. 4, GDPR. Article 8 regulates the tasks and powers of the CNIL. Point 2(c) of this Article establishes that this authority provides and publishes baseline rules and methodologies (recognised as "référentiels" and "méthodologies de référence") to ensure the security of personal data and to govern the processing of biometric, genetic and health data. According to this provision, the CNIL can define additional technical and organisational measures to be applied to the processing of biometric, genetic and health data, unless the processing is carried out by a controller on behalf of the State and acting in the exercise of official public tasks. The CNIL's guidance is therefore highly influential.

As regards derogations to data subjects' rights in light of Article 89, par. 2 GDPR, Articles 49, par. 3, 78 and 79 of the LIL refer to Articles 15, 16, 18 and 21 GDPR: derogations to these rights are possible insofar as such rights are likely to render impossible or seriously impair the achievement of the research purpose. This requirement explicitly follows the GDPR. The data controller should however implement specific safeguards, including restriction of access to personal data and anonymisation before disseminating the data or making them available.

Furthermore, specific rules are dedicated to personal health data in Title II, Chapter III, Section 3. Articles from 64 to 77 of the LIL in fact regard the processing of personal data in the medical field and include requirements on scientific research purposes (Sub-section 2 "special provisions concerning processing for the purposes of research, study or evaluation in the health field"). In more detail, Article 66 states that these provisions apply

[39] On the French approach to clinical research and the protection of personal data *see* e.g. F. Lesaulnier, 'Recherche en santé et protection des données personnelles à l'heure du Règlement général relatif à la protection des données' (2019) 158 Médecine & Droit, pp. 103-111; E. Toulouse, et al. 'French legal approach to clinical research' (2018) 37 Anaesthesia Critical Care & Pain Medicine 6, pp. 607-614.

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to processing operations that are carried out in the public interest, such as ensuring high standards of quality and safety of healthcare, medical products and medical devices[40]. Article 66, par. 2, directly mentions the CNIL's "référentiels" by specifying that processing in the medical field can be carried out only if it complies with the reference guidelines of the authority. After the necessary adjustment, the data controller should send a declaration of compliance to the CNIL. Alternatively, the data controller shall obtain a prior authorisation from the same authority (Art. 66, par. 3)[41]. This authorisation may refer to many processing operations having the same purposes, relating to identical categories of personal data and identical recipients (Art. 66, par. 4). Where the CNIL has not given its opinion within two months of the extension time, the application for authorisation shall be deemed to have been accepted, but this requirement does not apply to research purposes (Art. 66, par. 5). Either way, the data controller should involve the CNIL in the data processing. As an example, this provision applies to the "healthcare exception" or to clinical trials.

As regards research purposes in the medical field, Article 73 of the LIL establishes that when the processing complies with a "méthodologie de référence" of the CNIL, it may be carried out without the prior authorisation mentioned in Article 66; however, the data controller shall send a declaration of compliance to the CNIL. The authorisation is instead necessary for data processing that does not comply with any reference methodologies. This binding authorisation is issued by the CNIL within two months (and can be postponed for the same amount of time), after a consultation with one of the two ethical committees: the "Comité éthique et scientifique pour les recherches, les études et les évaluations dans le domaine de la santé" when the research does not involve a human being, or the "Comité compétent de protection des personnes mentionné à l'article L. 1123-6 du Code de la santé publique"[42] when the research involves a human (Article 76). Without authorisation, the processing is unlawful. This framework applies to both data processing carried out for primary research purposes and data processing that has secondary research purposes.

[40] This specification seems to evoke Art. 9, par. 2, lett. i), GDPR.

[41] The procedure is available at *https://declarations.cnil.fr/declarations/declaration/accueil.action;jsessionid=EDD5F30C677D70781F9F4CD2DBF8B0C2*.

[42] The Public Health Code unifies the applicable rules in the healthcare field, including the code of medical ethics.

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Thus, in the "référentiels"[43], meaning reference documents on processing activities[44], the CNIL lists the conditions under which processing of health data can be carried out, including a DPIA. In the six "méthodologies de référence" the authority defines reference methodologies, including measures and baseline technical standards, on particular processing situations carried out for research purposes in the medical field. These "méthodologies de référence" are domain-limited, often refer to categories of research projects and give great importance to the DPIA. When a processing falls under the conditions of one of the "méthodologies de référence", the data controller must comply with the baseline rules defined by the CNIL and submit a declaration of compliance[45]. Where applicable, the controller should apply online for prior authorisation ("demande d'autorisation de recherche") on the CNIL website by describing the processing operations and uploading documents[46]. "Méthodologies de référence" address research studies that are aimed at a public interest encompassing both private and publicly funded research[47].

In brief, "Méthodologie de référence" MR-001 is the reference document for data processing that uses health data, has a public interest, involves a human being, and requires the informed consent of a human participant in a scientific research study[48], while MR-003 for data processing has the same initial conditions, but does not require the informed consent of a human participant in a scientific research study and instead concerns non-interventional research and clusters of clinical trials of medicinal products[49]. MR-002 refers

[43] The information is summarised in the article at *https://www.cnil.fr/fr/quelles-formalites-pour-les-traitements-de-donnees-de-sante-caractere-personnel.*

[44] See e.g. CNIL, "Référentiel relatif aux traitements de données à caractère personnel destinés à la gestion des cabinets médicaux et paramédicaux", available at *https://www.cnil.fr/sites/default/files/atoms/files/referentiel_-_cabinet.pdf.*

[45] The procedure is available at *https://declarations.cnil.fr/declarations/declaration/accueil.action.*

[46] The procedure is available at *ibidem.*

[47] Examples of reasons of public interest in the area of public health are included in Art. 9, par. 2, lett. i) GDPR: "*protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products*". The specification on public interest excludes commercial purposes.

[48] Délibération n° 2018-153 du 3 mai 2018 portant homologation d'une méthodologie de référence relative aux traitements de données à caractère personnel mis en œuvre dans le cadre des recherches dans le domaine de la santé avec recueil du consentement de la personne concernée (MR-001) et abrogeant la délibération n° 2016-262 du 21 juillet 2016. MR-001 is available at *https://www.cnil.fr/fr/declaration/mr-001-recherches-dans-le-domaine-de-la-sante-avec-recueil-du-consentement.*

[49] Délibération n° 2018-154 du 3 mai 2018 portant homologation de la méthodologie de référence relative au traitement des données à caractère personnel mis en œuvre dans le cadre des recherches dans le domaine de la santé ne nécessitant pas le recueil du consentement de la personne concernée (MR-003) et abrogeant

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to non-interventional performance studies conducted on in vitro medical devices (IVDs)[50]. When the research does not involve human beings and refers to studies that re-use personal health data in light of a public interest, MR-004 applies[51]. Finally, MR-005[52] and MR-006[53] concern specific processing situations related to national programs for healthcare institutions, hospital federations and the healthcare industry.

Beyond the involvement and guidance of the CNIL, Article 77 of the LIL introduces an audit committee for the national health data system ("comité d'audit du système national des données de santé"), which defines strategies for making available personal data that are collected in the "système national des données de santé" (SNDS) for research purposes[54]. The SNDS covers almost the entire French population[55]. Thus, personal data are first

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la délibération n° 2016-263 du 21 juillet 2016. MR-003 is available at *https://www.cnil.fr/fr/declaration/mr-003-recherches-dans-le-domaine-de-la-sante-sans-recueil-du-consentement*.

[50] Délibération n° 2015-256 du 16 juillet 2015 portant homologation d'une méthodologie de référence relative aux traitements de données à caractère personnel mis en œuvre dans le cadre des études non interventionnelles de performances en matière de dispositifs médicaux de diagnostic in vitro (MR-002). MR-002 is available at *https://www.cnil.fr/fr/declaration/mr-002-etudes-non-interventionnelles-de-performances-concernant-les-dispositifs-medicaux*. As regards medical devices see Regulation (EU) 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. OJ L 117, 5.5.2017, and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. OJ L 117, 5.5.2017.

[51] Délibération n° 2018-155 du 3 mai 2018 portant homologation de la méthodologie de référence relative aux traitements de données à caractère personnel mis en œuvre dans le cadre des recherches n'impliquant pas la personne humaine, des études et évaluations dans le domaine de la santé (MR-004). MR-004 is available at *https://www.cnil.fr/fr/declaration/mr-004-recherches-nimpliquant-pas-la-personne-humaine-etudes-et-evaluations-dans-le*.

[52] Délibération n° 2018-256 du 7 juin 2018 portant homologation d'une méthodologie de référence relative aux traitements de données nécessitant l'accès par des établissements de santé et des fédérations aux données du PMSI et des résumés de passage aux urgences (RPU) centralisées et mises à disposition sur la plateforme sécurisée de l'ATIH (MR 005). MR-005 is available at *https://www.cnil.fr/fr/declaration/mr-005-etudes-necessitant-lacces-aux-donnees-du-pmsi-etou-des-rpu-par-les-etablissements*.

[53] Délibération n° 2018-257 du 7 juin 2018 portant homologation d'une méthodologie de référence relative aux traitements de données nécessitant l'accès pour le compte des personnes produisant ou commercialisant des produits mentionnés au II de l'article L. 5311-1 du code de la santé publique aux données du PMSI centralisées et mises à disposition par l'ATIH par l'intermédiaire d'une solution sécurisée (MR 006). MR-006 is available at *https://www.cnil.fr/fr/declaration/mr-006-etudes-necessitant-lacces-aux-donnees-du-pmsi-par-les-industriels-de-sante*.

[54] The rules on the SNDS are provided by Articles L. 1461-1 to Article L. 1461-7 of the *Code de la santé publique*.

[55] F. Lesaulnier, 'Recherche en santé et protection des données personnelles à l'heure du Règlement général relatif à la protection des données'.

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collected for healthcare purposes in the national ecosystem and then may be accessed for research purposes by internal or external researchers. Law no. 2019-774 of 24 July 2019 on the organisation and transformation of the health system[56], which modified the *Code de la santé publique*, changed the rules on the protection of personal health data by expanding the lawful research purposes by the use of the SNDS.

So, the French Government created the Health Data Hub (Plateforme des données de santé, hereinafter: HDH)[57], which is a public initiative and entity affiliated with the Ministry of Solidarity and Health and with the Ministry of Research[58]. The HDH is also a platform and single-entry point for health data access in the national health data system for research, studies, evaluation and innovation in the medical field[59]. The governance of this platform is composed of 56 entities of health data stakeholders, including the government, public bodies, patients' associations, and health research organisations. All the purposes of the HDH can be summarised as follows[60]:

1. collecting, organising and making available the data of the national health data system and promoting innovation in the use of health data;

2. informing patients, promoting and facilitating their rights, in particular with regard to the right to object, meaning the right to opt-out to the secondary use of their health data according to the framework of Article L. 1461-3 of the *Code de la santé publique*;

3. collaborating with the Scientific and Ethics Committee, which evaluates the research studies and with the CNIL, which develops methodologies for safeguarding data protection and security of health data;

4. carrying out the operations necessary for allowing access to the national health data system when a subject has obtained authorisation;

5. contributing to the dissemination of standards for data exchange, taking into account European and international standards;

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[56] Loi n° 2019-774 du 24 juillet 2019 relative à l'organisation et à la transformation du système de santé.

[57] Arrêté du 29 novembre 2019 portant approbation d'un avenant à la convention constitutive du groupement d'intérêt public «Institut national des données de santé» portant création du groupement d'intérêt public «Plateforme des données de santé». The CNIL released a preliminary opinion that is available at *https://www.legifrance.gouv.fr/cnil/id/CNILTEXT000038142154/*.

[58] *https://www.health-data-hub.fr/*.

[59] Art. L. 1461-1 Code de la santé publique.

[60] Art. L. 1462-1 Code de la santé publique.

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6. supporting, even financially, the project leaders and their stakeholders selected in the context of calls for projects.

Researchers, named "data users", can access datasets of health data for research purposes, but these data remain in the original repositories. In the HDH personal data are processed solely in a pseudonymised form. Only researchers carrying out public interest research with a specific and detailed project can access health data. Therefore, the researcher, as a public or private entity, should prove that the study is of public interest[61]. Other prerequisites to this access are the approval of the Scientific and Ethics Committee of the HDH (CESREES) and the authorisation of the CNIL. The details of the data processing and the research project are available on the HDH website in a concise, transparent, intelligible and easily accessible form that uses clear and plain language. This disclosure of information is compliant with the transparency and accountability principles of the GDPR (Article 5, par. 1, lett. a) and par. 2, Article 12. This mode of communication of information is particularly interesting since it combines information on the retrospective or prospective study with information required by Articles 13 and 14 of the GDPR, but it addresses society and not specific data subjects.

Taking into account the combination of all the requirements provided for scientific research activity in the medical field, it is worth pointing out that a legal or regulatory provision at the national level represents the basic ground for data processing in France. Hence, the data controller should provide adequate information to the data subjects and does not need to seek the consent of those involved in the scientific projects. The default basis is the legal provision at the national level in the LIL and the *Code de la santé publique* insofar as the research is aimed at a public interest, and the condition of the request of the consent is the exception. In fact, Article 75 of the LIL requires the informed and explicit consent of the data subject when the research involves genetic information, unless Article L. 1131-1-1 of the *Code de la santé publique* applies[62]. The data controller carrying out data processing with a public research purpose must comply with the CNIL's guidelines. When the research does not have a public interest, the applicable legal ground seems to be Article

[61] The website of the HDH specifies that the public interest of each project is assessed by an independent ethical and scientific committee that includes ethical and legal experts and representatives from patients' associations. *See* the information on this entity at *https://www.health-data-hub.fr/cesrees*.

[62] Art. L1131-1-1 concerns the examination of genetic characteristics of a person. It allows examination when the person has been informed and has not expressed her opposition. This is an "opt-out" approach, which is different from the "opt-in" approach of the LIL.

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9, par. 2, lett. j) GDPR and the consent of the data subject is required as a condition for starting the research lawfully.

Both French and Italian legal systems define specific rules for processing personal health data with medical research purposes. Looking at the processing situation where personal health data are first collected and processed under the "healthcare exception" provision, and the data controller seeks to use these data for a secondary medical research purpose, without anonymising them, meaning carrying out a prospective or retrospective study, it can be argued that in France the basic ground is law and it can operate through the central HDH platform; whereas in Italy the typical ground is Article 9, par. 2, j) and the consent of the data subjects is required as an additional safeguard, unless one of the exceptions mentioned above is applicable. In Italy the limitation to research that has a public interest is not included. Therefore, this legal framework does not distinguish between data processing activities that pursue scientific purposes, but involve different interests.

On the one hand, the additional condition of consent required by the two national frameworks is not conceived by the GDPR[63]. It may raise the "traditional problems" of unwitting consent, coerced consent, and incapacitated consent[64], and it may result in complex planning of research projects that involve several centres of different countries and cross-borders transfers of personal health data[65]. The revocability of consent may limit research studies creating uncertainty on what data can be lawfully used in the project phases. Thus, forms of broad consent are promoted by the authorities[66]. On the other hand, the GDPR leaves spaces to Member States to define the safeguards necessary to process personal data for research under Articles 9, par. 2, j) and 89 and the limitations with regard to the processing of data concerning health[67] (health research is, indeed, driven by the Member States national competences on public health).

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[63] *See* section 2.

[64] *See* G. Schneider and G. Comandé, 'Differential Data Protection Regimes in Data-Driven Research: Why the GDPR Is More Research-Friendly Than You Think', cit., pp 12-15; D. Peloquin *et al.*, 'Disruptive and avoidable: GDPR challenges to secondary research uses of data" '(2020) 28 Eur J Hum Genet 28, pp. 697–705.

[65] A typical example is a research project funded by the Horizon Programmes. *See* at *https://ec.europa.eu/programmes/horizon2020/en/h2020-sections-projects*.

[66] *See* the EDPB, "Preliminary Opinion on data protection and scientific research", cit., and the Proposal for a Regulation of the European Parliament of the Council on European data governance, *supra* note no. 5.

[67] *See* section 2 and also Article 9, par. 4 GDPR.

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France and Italy adopted different approaches on the conditions for secondary processing of personal health data. The French approach to research in the medical field is centralised since a national public entity (i.e. the HDH) allows the use of personal health data already collected for healthcare purposes. Conversely, in Italy the approach is decentralised. Therefore, research stakeholders should identify the suitable path.

Despite this difference, as in the Italian framework, in France it is highly likely that a DPIA will be required as an *ex ante* instrument of compliance. In addition, both legal frameworks often require data processing to be subject to prior consultation or authorisation from the DPAs. In this sense, the CNIL has a defined online procedure and several reference documents to guide the request for authorisation. This framework also includes the declaration of compliance as a starting condition for the data processing.

Finally, the CNIL and Italian DPA lay down specifications on data concerning health and provide guidance on research purposes in the medical field since both national laws (LIL and IDPC) define specific powers and tasks in this particular domain. French specifications are more detailed and complex, and include ethical bodies that are external to the research organisations, but coordinated at the national level. Instead, where applicable, Italian researchers should obtain the opinion of the ethical committee internal to the organisation they are part of[68].

The next section proposes a proactive approach that is focused on the Italian framework, but can be applied to other frameworks with appropriate adjustments since it follows the requirements of the GDPR and the data protection by design principle. So, it takes into account the rules described in sections 2 and 3. It also uses the transparency approach of the HDH mentioned in section 4: it represents an advanced example of how information on the research study can be provided online to data subjects and citizens by combining characteristics on data processing with details of the scientific project. The proposed legal-technical solution clarifies the legal ground of the data processing, and uses the explicit consent as additional safeguard laid down in Italian framework, trying to avoid the above-mentioned possible criticalities. It involves a mobile application as intermediary that is already used by citizens for healthcare purposes and that fosters an interdisciplinary and privacy by design implementation. The solution is integrated with a virtual coaching system that interacts with the user by sending messages on active research projects to be joined and on all the information related to the data processing activities. By means of this

[68] In fact, Art. 110 IDPC does not institute a central ethical committee like the French CESREES, but it refers to "*the competent ethics committee at the territorial level*".

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approach, the secondary use of personal health data may be boosted. The management of the data processing, including its legal grounds and conditions, will be carried out in a way that considers both healthcare providers' and researchers' perspectives.

5. A proactive legal-technical solution: a data protection by design approach

Healthcare provision, medical scientific research and data processing of health data have been deeply affected and revolutionised in the digital age [69]. In the medical field, digitalisation is more than a technical process: on the one hand, it involves Information and Communication Technologies (ICTs) and algorithms, including Artificial Intelligence, and, on the other hand, it leads to a considerable impact on healthcare-related processes, practices, and services at the organisational level[70]. The use of ICTs in health products, services and processes is identified by the concept of *e-health*[71]. E-health solutions refer to

[69] *See ex multis* J. Madir, *Healthtech. Law and Regulation* (Elgar Commercial Law and Practice, 2020); S. Melchionna and F. Cecamore, 'Le nuove frontiere della sanità e della ricerca scientifica', in Panetta (ed.), *Circolazione e protezione dei dati personali, tra libertà e regole del mercato. Commentario al Regolamento UE n. 2016/679 (GDPR) e al novellato D.lgs. n. 196/2003 (Codice Privacy)* (Giuffrè Francis Lefebvre, 2019), pp. 579-620; D. Sigulem *et. al*, 'The New Medicine: From the Paper Medical Record to the Digitized Human Being', in de Fátima Marin (ed.), *Global Health Informatics* (Elsevier, 2017), pp. 152-167; W. W. Lowrance, *Privacy, confidentiality, and health research*, Vol. 20 (Cambridge University Press. 2012).

[70] *See* further EXPH, Expert Panel on effective ways of investing in Health, "Assessing the impact of digital transformation of health services", Publications Office of the European Union, 2019.

[71] *See* the definition of e-health in the European Commission, "eHealth Action Plan 2012–2020. Innovative healthcare for the 21st century", 2012, p. 3: "*The use of ICT in health products, services and processes combined with organisational change in healthcare systems and new skills, in order to improve health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health*".

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multiple technologies, such as clinical information systems, electronic health records, personal health records[72], telemedicine systems[73], and mobile applications[74].

The digital processing of health data creates both enormous opportunities and critical challenges. E-health can theoretically improve the efficiency and quality of healthcare provision[75] and can also facilitate scientific research, which can potentially access and share a greater amount of personal health data than before (i.e. Big Data)[76]. At the same time,

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[72] On these systems *see ex multis* G. Bincoletto, 'Data Protection Issues in Cross-Border Interoperability of Electronic Health Record Systems within the European Union' (2020) 2 Data & Policy 3, pp. 1-11; G. Bincoletto, 'A Data Protection by Design Model for Privacy Management in Electronic Health Records', in: *Privacy Technologies and Policy, 7th Annual Privacy Forum*, Lecture Notes in Computer Science, (Springer International Publishing, 2019), pp. 161-181; G. Comandé, L. Nocco, and V. Peigné, 'An empirical study of healthcare providers and patients' perceptions of electronic health records' (2015) 59 Computers in Biology and Medicine, pp. 194-201; C. George, D. Whitehouse, and P. Duquenoy, *eHealth: legal, ethical and governance challenges* (Springer Science & Business Media, 2012); P. Guarda, *Fascicolo sanitario elettronico e protezione dei dati personali*, Vol. 94 (Quaderni del Dipartimento di Scienze Giuridiche, 2011); C. P. Hartley and E. Douglass Jones, *EHR implementation: A step-by-step guide for the medical practice* (American Medical Association, 2012); N. P. Terry and L. P. Francis, "Ensuring the privacy and confidentiality of electronic health records" (2007) U. Ill. L. Rev., pp. 681-736; E. J. Bieber, F. M. Richards and James M. Walker, *Implementing an electronic health record system* (Springer, 2005).

[73] On telemedicine *see ex multis* C. Botrugno, 'Telemedicine in daily practice: Addressing legal challenges while waiting for an EU regulatory framework' (2018) 7 Health Policy and Technology 2, pp. 131-136; C.L. Wen, 'Telemedicine, eHealth and Remote Care Systems', in de Fátima Marin (ed.), *Global Health Informatics* (Elsevier, 2017), pp. 168-194; P. Guarda, 'Telemedicine and Application Scenarios: Common Privacy and Security Requirements in the European Union Context' (2015) *Trento Law and Technology Research Group Research Paper n. 23*; C. Ionescu-Dima, 'Legal challenges regarding telemedicine services in the European Union', in Carlisle et al. (ed.), *eHealth: Legal, Ethical and Governance Challenges* (Springer, 2013), pp. 107–133.

[74] On mobile health *see ex multis* T. Mulder, 'Health apps, their privacy policies and the GDPR' (2019) 10 European Journal of Law and Technology 1; E. Mantovani *et al.*, 'Towards a Code of Conduct on Privacy for mHealth to Foster Trust Amongst Users of Mobile Health Applications', in Leenes (ed.), *Data Protection and Privacy: (In)visibilities and Infrastructures* (Springer, 2017), pp. 81–106; European Commission, "Green paper on mobile Health", COM(2014) 219 final, 2014.

[75] *See* e.g. W. Ricciardi, 'Assessing the impact of digital transformation of health services: Opinion by the Expert Panel on Effective Ways of Investing in Health (EXPH)' (2019) 29 European Journal of Public Health Supplement 4, ckz185–769; 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 enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society", COM (2018), 233 final, 2018.

[76] On Big Data and the use of artificial intelligence (AI) in the medical field and data protection issues *see ex multis* P. Guarda and L. Petrucci, 'Quando l'intelligenza artificiale parla: assistenti vocali e sanità digitale alla luce del nuovo regolamento generale in materia di protezione dei dati' (2020) 2 BioLaw Journal-Rivista di BioDiritto, pp. 425-446; P. Guarda, '"Ok Google, am I sick?": artificial intelligence, e-health, and data protection regulation' (2019) 15 BioLaw Journal-Rivista di BioDiritto 1, pp. 359–375; R: Pierce, 'Machine learning for diagnosis and treatment: Gymnastics for the GDPR' (2018) 4 Eur. Data Prot. L. Rev., pp. 333-343; A. Ferretti, M. Schneider, and A. Blasimme, 'Machine Learning in Medicine: Opening the New Data

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security, privacy and data protection represent challenging issues to consider. As mentioned, data processing operations must guarantee the right to data protection of data subjects and then comply with the requirements laid down by the GDPR and by national data protection regulations[77]. It has been shown that the GDPR lays down specific rules on the processing of personal health data and on the processing carried out for scientific research purposes, and that national laws develop the requirements.

Moreover, the GDPR incorporates an ambitious provision and binding obligation for data protection by design (DPbD), which should play a central role when projecting any data processing within an e-health system, especially in the case of secondary processing of health data for medical scientific research. Article 25, par. 1, GDPR states that the data controller shall implement appropriate technical and organisational measures that are designed to achieve data protection principles in an effective manner and to integrate the necessary safeguards into the processing at the time of the determination of the means for processing and at the time of the processing itself[78]. To this end, the data controller can take into account various criteria, namely: the state of the art, the cost of implementation and the nature, scope, context and purposes of processing, and the risks of varying likelihood and severity for rights and freedoms of natural persons posed by every processing operation. The evaluation and assessment of the risks must be preliminary and done very carefully.

Protection Black Box' (2018) 4 Eur. Data Prot. L. Rev., pp. 320-332; A. Stylianou and M. A. Talias, 'Big data in healthcare: a discussion on the big challenges' (2017) 7 Health and Technology 1, pp. 97-107.

[77] Only after the anonymisation of personal data, the activities fall outside the scope of the GDPR. An implicit premise is that the data processing falls under the material and territorial scope of the GDPR (Art. 2 and 3).

[78] On data protection by design *see* L. A. Bygrave, 'Chapter IV Controller and Processor (Articles 24-43). Article 25. Data protection by design and by default', in Kuner et. al (ed.), *The EU General Data Protection Regulation (GDPR): A Commentary*, cit., pp. 571-581; A. E. Waldmam, 'Data Protection by Design? A Critique of Article 25 of the GDPR' (2020) 53 Cornell Int'l L.J., pp. 147-167; I. S. Rubinstein and N. Good, 'The trouble with Article 25 (and how to fix it): the future of data protection by design and default' (2019) International Data Privacy Law, pp. 1–20; European Data Protection Board, 'Guidelines 4/2019 on Article 25 Data Protection by Design and by Default, 2019 available at *https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-42019-article-25-data-protection-design-and_en*; G. Bincoletto, *La privacy by design* (Aracne Editrice, 2019); European Data Protection Supervisor, 'Opinion 5/2018, Preliminary Opinion on privacy by design', 2018 available at *https://edps.europa.eu/data-protection/our-work/publications/opinions/privacy-design_en*; L. Jasmontaite *et al.*, 'Data protection by design and by default: Framing guiding principles into legal obligations in the GDPR' (2018) 4 Eur. Data Prot. L. Rev., pp. 168-189, p. 177; A. Tamó-Larrieux, *Designing for privacy and its legal framework: data protection by design and default for the internet of things*, Law, Governance and Technology Series (Springer, 2018); L. A Bygrave, 'Data protection by design and by default: deciphering the EU's legislative requirements' (2017) 4 Oslo Law Review 2, pp. 105-120.

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Data controllers should apply DPbD on a case-by-case basis since Article 25 GDPR does not provide a "one-size-fits-all" approach, and instead requires proper management of every aspect and characteristic of data processing activities. However, beyond the complexity and the vagueness of the text of the provision, a concrete implementation of DPbD can be achieved through an interdisciplinary approach. Interdisciplinarity is indeed necessary to simultaneously take into account the state of the art of the technology adopted for the data processing and the related engineering methodologies and approaches, the management of processing activities at the organisational level, and the applicable legal requirements in the data protection framework[79]. Solutions should then combine legal and technical perspectives.

By trying to embrace legal and technical perspectives, as well as research needs, in a unique solution, we have tried to assess the aspects of the national contexts mentioned above. The proactive solution that will be proposed below has been elaborated through an interdisciplinary investigation[80]. The legal-technical solution is applicable in multiple

[79] On the interdisciplinary method *see* G. Pascuzzi, *La creatività del giurista. Tecniche e strategie dell'innovazione giuridica* (Zanichelli, 2013).

[80] The solution was developed in collaboration with the "eHealth" Research Units of the Italian Fondazione Bruno Kessler (FBK), and in particular during the activities carried out within the Competence Center on Digital Health "TrentinoSalute4.0". In 2017 the local government of the Autonomous Province of Trento (Provincia Autonoma di Trento - PAT), the local healthcare provider Azienda Provinciale per i Servizi Sanitari (APSS) and the research institute Fondazione Bruno Kessler established the Competence Center on Digital Health "TrentinoSalute4.0" to identify new organisational models and technological solutions in the e-health domain, to study the legal aspects and evaluate their impact, and to transform technical-organisational solutions into innovative services for the healthcare sector. These objectives of "TrentinoSalute4.0" are reported at *https://trentinosalutedigitale.com/en/*. The solution was tested on the platform TreC+, which is based on the concept of personal health record. On the concept of personal health record *see* R. Saripalle, C. Runyan and M. Russell, 'Using HL7 FHIR to achieve interoperability in patient health record' (2019) 94 Journal of biomedical informatics, 103188. The solution is the advanced version of the Personal Health Record (PHR) TreC developed in 2008. The previous version of the application, TreC, is described in C. Eccher *et al.*, 'TreC platform. An integrated and evolving care model for patients' empowerment and data repository' (2020) 102 *Journal of biomedical informatics*, p. 103359. *See* also the website of TreC at *https://trec.trentinosalute.net/fast-trec*. TreC+ is currently in a release phase, and the following proposed solution is not yet fully implemented. For further details on PHR in the Italian legal system, *see* also P. Guarda and R. Ducato, 'From Electronic Health Records to Personal Health Records: emerging Legal Issues in the Italian Regulation of eHealth' (2016) International Review of Law, Computers & Technology, pp. 271-285. For the sake of clarity, the data controller of TreC+ platform is the local healthcare provider (Azienda Provinciale per i Servizi Sanitari - APSS). This local healthcare provider conceived the platform with the local government Autonomous Province of Trento and FBK. APSS stores clinical documents of citizens resident in the Province in the hospital information system (SIO, Sistema Informativo Ospedaliero). The aim of the TreC+ platform is to improve patients' empowerment by allowing access to and management of personal data (e.g. referrals, laboratory tests, drug prescriptions) and of services provided by APSS (e.g. prescriptions, telemonitoring, payments, access to parameters measured by medical devices). The digital ecosystem encompasses a web-based platform with a dashboard that is

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contexts and may be a model for enhancing interoperability between different solutions adopted at the local level. In fact, it is an example of application of the data protection by design concept during the development of an e-health system that processes personal health data for the primary healthcare purpose, but whose data might be secondarily used for research purposes in the medical field.

The core pillar of this solution is the use of an e-health mobile application as a technological intermediary to enrol citizens in research projects (retrospective or prospective). A mobile application is a well-known tool for most people and healthcare providers are using it for healthcare purposes ever more frequently. Deploying this tool improves acceptability and ease of access. If we assume this tool as an intermediary component, we enable the processing of personal health data by the local healthcare provider for secondary research purposes, citizens are involved in modern "citizen science"[81], and the local government creates an "alliance with the citizens" for the proactive use of personal health data in scientific research. In this way, public entities lead the process and support scientific innovation.

It should be noted that the solution does not apply Article 110 IDPC since it refers to scientific research purposes in the medical, biomedical and epidemiological fields that are

controlled by the medical doctor/healthcare staff, a mobile e-health application (hereinafter: TreC+) and a web-based platform for patients. In TreC+ the user plays an active role: she can access and manage personal data, but can also generate data and store information. TreC+ actually allows access to the data collected in the Italian EHR, to the data provided by the patient in the PHR (e.g. weight, blood pressure, symptoms, allergies), and to APSS's services, including telemedicine services (e.g. teleconsultation, telemonitoring). On "Fascicolo Sanitario Elettronico" *see* Articles 12, 13, and 13-bis of Decreto-legge 18 ottobre 2012, n. 179 e legge di conversione 17 dicembre 2012, n. 221 recante "Ulteriori misure urgenti per la crescita del Paese". G.U. Serie Generale n. 294 del 18-12-2012 - Suppl. Ordinario n. 208; Decreto del Presidente del Consiglio dei Ministri 29 settembre 2015, n. 178 Regolamento in materia di fascicolo sanitario elettronico. G.U. Serie Generale n. 263 del 11-11-2015; and Garante per la protezione dei dati personali, Linee guida in tema di fascicolo sanitario elettronico e di dossier sanitario del 16 luglio 2009, G.U. n. 178 del 3 agosto 2009, Registro delle deliberazioni n. 25 del 16 luglio 2009. *See* also G. Vergottini and C. Bottari, *La sanità elettronica* (Bononia University Press, 2018); G. Carro, S. Masato, and M. D. Parla, *La privacy nella sanità* (Giuffrè, 2018); L. Califano, 'The Electronic Health Record (EHR): Legal framework and issues about personal data protection' (2017) 19 Pharmaceuticals Policy and Law 3-4, pp. 141–159; C. Faralli, R. Brighi, M. Martoni *et al.*, *Strumenti, diritti, regole e nuove relazioni di cura: Il Paziente europeo protagonista nell'e-Health* (G. Giappichelli Editore. 2015); M.G. Virone, *Il Fascicolo Sanitario Elettronico. Sfide e bilanciamenti tra Semantic Web e diritto alla protezione dei dati personali* (Aracne Editrice, 2015); G. Comandé, L. Nocco, and V. Peigné, 'Il fascicolo sanitario elettronico: uno studio interdisciplinare' (2012) 1 Rivista Italiana di Medicina Legale (e del Diritto in campo sanitario), pp. 106–121.

[81] On this concept at the European level *see https://ec.europa.eu/digital-single-market/en/citizen-science.* At the theoretical level *see* S. Hoffman, 'Citizen science: the law and ethics of public access to medical big data' (2015) 30 Berkeley Tech. LJ 3, pp. 1741-1805.

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not carried out on the basis of a legal or regulatory provision at the national or European Union level. In addition, through the use of a mobile application downloaded by the majority of citizens of a local area to access healthcare services, it is difficult to prove a "disproportionate effort" in informing the data subjects. The solution does not even refer to Article 110-bis IDPC since a typical local healthcare provider is a public institution of hospitalisation and care. However, it takes into account all the research studies involving personal health data and even studies using anonymised data since it provides an information layer and a dedicated website that make all the relevant information available in a transparent manner.

More specifically, when a user downloads an e-health application that gives access to and manages personal data and health-related services of a local healthcare provider, she logs in with her credentials[82] and receives various notices, including information on the use of the app (e.g. as a PHR, FSE, and tool to manage services) and the modular and user-friendly privacy policy. The information on the app will state that it is a tool requesting participation in research projects. The privacy policy will link to the complete policy in a dedicated website, and will specify that the application may profile the user through the data entered and processed in order to propose research projects for which the user is eligible. After viewing the privacy policy, the user must give consent for using the app and may agree to processing related to the FSE (feeding and levels of consultation of the data) and to automatic profiling. The denial of this consent does not affect the proposed solution since, in the case of denial, the research proposal will be sent in another way, which will be described soon.

While using the application, the user will be able to generate different information about her health and medical history. A virtual coaching system integrated in the app will interact with the user by sending messages. A chatbot will invite and guide the user to fill information in the profiling form, which will be a questionnaire on medical history, pathologies, habits and lifestyle, etc. In addition, the user will receive messages from the chatbot about information related to active research projects that do not need the data subjects' consent (e.g. research based on a regulatory provision, research on anonymised data). So, push notifications will be used to send messages relating to the existing research studies that are also described in a website following the French approach of Health Data Hub. The details of the data processing and the research projects will be combined on the

[82] The user must be a citizen enrolled in the health registry. The citizen must have the credentials to use the application. Moreover, the explanation of the solution presumes that the user is not a minor.

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website as specific sheets using concise, transparent, intelligible and easily accessible forms in clear and plain language that highlight characteristics of the studies and of the processing operations. As a result, citizens can be informed about research activities in the local environment.

When a physician/researcher from the local healthcare provider defines a structured research project that requires the use of health data of patients, after obtaining the approval of the competent ethics committee within the local territory, which may be a preliminary step, the number of people to be enrolled (sample size) and the inclusion criteria necessary for research will be specified. A special dashboard linked to the app checks the eligible users that have accepted to be profiled. If the number of eligible users is sufficient, the research proposal will be sent through the chatbot only to these profiles. If the number of eligible users is not sufficient, the chatbot notification will be activated for all the active subscribers regardless of profiling. The chatbot should then have the function of creating a questionnaire based on the eligibility requirements of the specific study for non-profiled members in order to assess actual eligibility.

If the user has consented to the profiling and is among the eligible persons, the chatbot will send a message inviting her to participate in the research project. If the user has not given consent to profiling, the chatbot will send messages asking about general interest in participating in the specific research project and further messages for filling in the specific questionnaire to verify eligibility.

Anyway, if eligible, the user, guided by the chatbot, will view the information on the research project and the related detailed privacy policy with a reference to the full policy and information sheet on the website. Then, the user will be able to give explicit consent to participate as a data subject and consent as a human participant in a scientific research study, directly in the app. The user must give privacy consent to the specific project and to participate in the project. The denial affects the lawfulness of processing and prevents any research activity.

Afterwards, the user will receive messages about scheduled project events through the chatbot. By entering the website, the user will be able to withdraw her participation in the project by sending an email to the project manager and data protection officer indicated there. It will be specified that the personal data that have been processed for research purposes up to that moment will remain in the project until its end, but that new data will not be sent to the project.

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At the end of the research project, the user will receive a message to access the project sheet on the website where she will be able to view information about the results, publications, reports and impact of the study. The user may also receive an invitation to respond to an evaluation survey about participation in the research.

The solution described complies with the requirements of the GDPR and with the data protection by design obligation since principles of Article 5 GDPR are fulfilled. The data processing is lawful on the basis of Article 9, par. 2, lett. j) and explicit consent is collected as an additional safeguard that respects the essence of the right to data protection and protects fundamental rights and interests of the data subjects while fostering scientific research. Interpreting Article 110 IDPC *a contrario*, in Italy for the activities carried out under Article 9, par. 2, lett. j) GDPR, the request for consent is binding unless one of the exceptions apply. In the "Scientific research requirements" the *Garante* confirms that consent is required unless the research is carried out on the basis of a legal provision or when it is not possible to obtain it for particular and exceptional reasons.

Moreover, the solution is fair and transparent since detailed information is provided to the data subject by push notifications in the app, even when consent is not required, and the research study is grounded on a regulatory basis by exception. The purpose limitation principle is guaranteed since the purpose of the research study is specified and explicit in the privacy policy and sheet provided to the user when requesting participation and it is always available on the website. Only personal data that are relevant to the research study will be processed (data minimisation); then, the other personal data collected and processed in the application are kept aside and not made available to the researcher. This also complies with the data protection by default requirement (Art. 25, par. 2, GDPR). In addition, the security and storage limitation principles are protected by the measures implemented in the application, but also at the platform level since the activities are carried out in a more complex scenario that does not use only an app but is connected to a digital e-health ecosystem of a local healthcare provider. For the sake of completeness, it should be noted that the other requirements of the GDPR will be implemented at the organisational level, including the DPIA, the creation of the record of the processing activities, the agreements between controllers and any processors, the management of data subjects' rights, and the designation of the DPO. Personal data is not transferred either to third countries or to international organisations.

In sum, an e-health application used by a local healthcare provider in a digital health context can be implemented as the technological intermediary that can be used to enrol citizens in scientific projects in the medical field, provide information and, where

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applicable, collect their consent as data subjects and human participants, and manage several aspects of the data processing. Through this tool, the data subject will be able not only to express consent, but also to withdraw it in the future, and to access information on projects involving their data and on other projects that may indirectly impact their health, also receiving push messages on new projects. The controller, a local healthcare provider, can set up many prospective and retrospective research studies, and find participants by using an e-health application. Consent is obtained by the use of a chatbot in the same app. According to this solution, the imbalance of power between the controller and the data subjects seems to be avoided and the data protection by design obligation fulfilled.

6. Conclusive remarks

The issues related to fostering medical scientific research as a secondary use of personal health data are intrinsically characterized by interdisciplinarity. It is challenging to strike an appropriate balance between the promotion of research and the protection of a particular category of personal data. Several and complex rules and conditions are established by the legal frameworks at EU and Member States levels. Facing the analysis of concrete application scenarios and being able to envisage reliable solutions of a technical-legal nature require an innovative and holistic approach that creates a synergy of the various types of knowledge involved.

Data protection by design, therefore, plays a fundamental role. The correct definition of the data protection risks and the adoption, from the beginning, of technical and organisational measures aimed at implementing principles and rights relating to the protection of personal data in an appropriate and effective manner are essential in anticipating and minimising the possible risk of unlawful processing. However, this implementation is very complex, especially in the new e-health context.

A holistic approach but also and above all a proactive one: in order to overcome the complexity and legal nebulosity that governs the possible use of health data for secondary purposes in the medical field, it is more advisable to focus on proactive solutions that emphasise the importance of patients' empowerment, placing them truly at the centre of the flows and the decisions relating to the processing of data concerning them.

In this paper we have tried to analyse the reference regulatory framework in a comparative way by taking into account both the EU level and two Member State's laws. The compatibility of the research purpose does not leave out the need to identify the applicable legal ground for processing and to consider all the binding conditions that apply to the special category of personal data and to the particular activities of research studies.

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A data protection framework should provide rules to enhance scientific research and not be an obstacle to it.

We also attempted to envisage a proactive legal-technical solution, which applies data protection by design in the development of an e-health system that processes personal health data for the primary healthcare purpose and can be used as a technological intermediary to enrol citizens in research projects. This solution may concretely support researchers and professionals involved in medical research projects since: it defines a clear basis for processing personal data for secondary research purposes; it uses the additional safeguards of the explicit consent (as provided by the Italian framework); it gives high importance to providing complete and transparent information (i.e. as planned by the French national initiative). Such an approach is in line with the GDPR *favour* on fostering secondary uses of personal data and enhances scientific research by involving as many subjects as possible in a safe and compliant environment.

However, the success of this type of initiative relies on the direct involvement of the patient/citizen who must be made aware of the benefits in general terms of scientific research and of the fact that her direct participation in this type of activities is the key to their success. Communication campaigns at the European, national and local levels should attract the interest of citizens regarding categories of research studies and the use of e-health solutions.

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Food safety e intelligenza artificiale

Sabrina Lanni (*)

Abstract

Il lavoro affronta le diverse prospettive per realizzare la *food safety* attraverso l'uso dell'intelligenza artificiale e delle nuove tecnologie, ponendo attenzione alle istanze di consumo sostenibile che prendono forza nel quadro giuridico europeo, anche attraverso la cd. '*Farm to Fork Strategy*', e che richiamano il giurista ad una riflessione sull'uso dell'intelligenza artificiale nel crocevia tra *food law* e *consumer law*.

Table of Contents

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Keywords

Food Safety – Consumer Rights –Artificial Intelligence – New Food Technologies – Sustainability

1. L'intelligenza artificiale nel crocevia tra *food law* e *consumer law*

Dal punto di vista comparatistico si è messo in risalto come la locuzione *food safety*, che è entrata prepotentemente in circolazione nel lessico giuridico, sia più ampia e più precisa dell'omologa italiana di sicurezza alimentare. Il rapporto tra lingua e diritto sottolinea come la locuzione stessa indichi, non solo la sicurezza igienico-sanitaria dei prodotti alimentari immessi in commercio, ma anche la sicurezza in termini tossicologici e nutrizionali, come pure la sicurezza delle informazioni e la trasparenza delle stesse nelle diverse fasi della filiera agro-alimentare[1].

Si tratta di un concetto macro-comparativo che ha ispirato la politica europea della *food law* così come tracciata dal Reg. CE 178/2002, e che nello specifico ha spronato il rafforzamento della fiducia dei consumatori nel mercato, come pure della loro protezione in termini di tutela preventiva del diritto alla salute[2]. Mentre nel sistema

[1] In relazione alle peculiarità della *food safety* tra i lavori più recenti cfr. E. Thomann, *Customized Implementation of European Union Food Safety Policy. United in Diversity?*, Palgrave Macmillan, 2019; G.B. Chen-R. Price (eds.), *Regulatory Issues in Organic Food Safety in the Asia Pacific*, Springer, 2020; F. Albisinni, *Strumentario di diritto alimentare europeo*, Utet, 2020. Sui caratteri della sicurezza alimentare europea e sul suo sconfinamento dalla sicurezza del prodotto alla sicurezza dell'informazione cfr. E. Rook Basile, *La mano invisibile del rischio*, in AA.VV., *I diritti della terra e del mercato agroalimentare. Liber amicorum Alberto Germanò*, II, UTET, 2016, p. 1088.

[2] Il Regolamento, che rappresenta una sintesi dei principi e delle regole per la tutela del consumatore di prodotti alimentari, indica i limiti della libertà di informazione imposta ai produttori in tema di sicurezza alimentare, e rafforza il diritto dei consumatori alla corretta informazione rispetto a quanto già riconosciuto, in via generale, dalla Dir. CEE 374/1985 e dal Reg. EU 1924/2006 (cruciale è il suo collegamento con problematiche di grande impatto sociale come quelle della BSE, su cui cfr. E. Vos, *EU Food Safety Regulation in the Aftermath of the BSE Crisis*, in *Journal of Consumer Policy*, 23, 2000, pp. 227-255). Esso vieta tutti quei comportamenti che possono essere diretti ad ostacolare le scelte consapevoli dei consumatori in relazione agli alimenti che consumano (art. 8) e ribadisce l'importanza di una corretta informazione attraverso l'etichettatura, al fine della qualificazione di

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per danno da prodotto difettoso delineato dalla Dir. CEE 374/1985 (e poi dalla Dir. CE 95/2001) emergeva la responsabilità solo se il produttore aveva messo in circolazione il prodotto, e "per messo in circolazione" si intende ai sensi dell'art. 118 cod. cons. la consegna del bene all'acquirente, anche solo in visione o in prova, oppure la consegna al vettore o allo spedizioniere per il trasporto all'acquirente, viceversa nel sistema delineato dal Reg. CE 178/2002 la responsabilità per la salute del consumatore emerge a prescindere dalla immissione in commercio del prodotto alimentare, ritenendosi sufficiente la "detenzione per la vendita" del prodotto alimentare, compresa la cessione a titolo gratuito di alimenti[3].

Negli obiettivi della *food safety* emerge una finalità di tutela preventiva del diritto alla salute e degli interessi dei consumatori alla preservazione della salute, che è propria non solo del diritto alimentare, essendo la stessa consona con gli obiettivi di garanzia del diritto stesso più ampiamente pubblicistici, oltre che con gli obiettivi precipui del diritto dei consumatori[4]. Nondimeno emerge attraverso il Reg. CE 178/2002 un'accentuazione della responsabilità e dei suoi contenuti, anche avendo riguardo ai soggetti coinvolti e, in primo luogo, della responsabilità dell'operatore del settore alimentare (considerando 30 e art. 17). La finalità menzionata rafforza il carattere

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un alimento come sicuro e commerciabile (art. 14, par. 3, lett. B), nonché la rilevanza della correttezza delle comunicazioni commerciali (art. 7) e delle forme di garanzia/sanzione (sul tema si rinvia agli atti del Workshop AIDA-EFLA '*The Implementation of Regulation (EU) 1169/2011 in some Member States and the Sanction Models Adopted*', in *Rivista di diritto alimentare*, 1/2020, open access).

[3] Il confronto tra Dir. CEE 374/1985 e Reg. CE 178/2002 è delineato in M.P. Genesin, *La responsabilità primaria dell'operatore del settore alimentare in relazione alla* food safety, in *Responsabilità civile e previdenza*, 3/2010, pp. 809-826; L. González Vaqué, *The Proposed EU Consumer Product Safety Regulation and its Potential Conflict with Food Legislation*, in *European Food and Feed Law Review*, 3, 2014, pp. 161-70.

[4] Molteplici i riferimenti in sede giurisprudenziale, tra i quali la sentenza *Greenpeace Francia et al. C. Ministère de l'Agriculture et de la Pêche e al.* (cfr. sentenza del 21 marzo 2000, causa C-6/99, con nota in *Common Market Law Review*, 37, 2000, pp. 1427-1432) dove la Corte di Giustizia, intervenendo sull'immissione in commercio di sementi geneticamente modificate di granoturco, ha riconosciuto la concreta applicazione del principio di precauzione nelle problematiche della sicurezza alimentare e degli organismi geneticamente modificati (in argomento cfr. R. Saija, *Gli Organismi Geneticamente Modificati nel diritto dell'Unione Europea: il ruolo del principio di precauzione ed il controverso rapporto tra Autorità e Libertà*, in *Revista Electronica de Direito*, 2/2017, open acces). Nella prospettiva precauzionale si colloca l'adozione della Dir. EU 412/2015 la quale, modificando la Dir. CE 18/2001, ha riconosciuto la possibilità per gli Stati membri di poter modificare o limitare le autorizzazioni per la coltivazione sui loro territori di organismi geneticamente modificati, nonostante questi siano stati autorizzati a livello europeo.

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sanzionatorio e afflittivo in caso di violazione dei paradigmi propri della legislazione alimentare europea, e quindi in primo luogo la *food safety*. Si potrebbe dire che la responsabilità per la tanto temuta '*food unsafety*' si distingue dal sistema di responsabilità configurato per la *consumer law*, poiché il legislatore europeo, rispetto alla connotazione di una tutela 'ex post' degli interessi del consumatore, ha posto un'enfasi maggiore sulla 'ex ante' degli interessi stessi.

Attraverso l'art. 7 del Reg. CE 178/2002 il legislatore europeo ha cercato di bilanciare le esigenze del commercio con quella della buona salute delle persone[5], cosicché prevenzione, prevedibilità e rintracciabilità sono le tre parole chiave che si accavallano e si rincorrono nella legislazione europea sulla *food law*. Esse, ancor prima di trovare un ulteriore addentellato normativo nell'art. 1 del TFUE, si scorgono tra la trama e l'ordito che sono stati tracciati nell'ambito della *food safety* dalle Corti europee[6]. Si tratta di un'impostazione palesemente in linea con le finalità principali del Reg. CE 178/2002, vale a dire prevedere regole utili a minimizzare il rischio alimentare nel mercato europeo, come emerge chiaramente dall'art. 6 e, in relazione ai doveri dell'operatore del settore alimentare, dagli artt. 14 e ss.[7]. Le riflessioni che seguono partono da un interrogativo di fondo: attraverso quali modalità è tecnicamente possibile raggiungere gli obiettivi di 'prevenzione', 'precauzione' e 'rintracciabilità'? Come dire che l'incidenza dell'intelligenza artificiale può rappresentare null'altro che

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[5] Sul concetto di salute e sul suo avvicinamento all'ampia definizione elaborata in sede internazionale dove l'uomo è preso in considerazione nel suo complesso e non solo in relazione al suo aspetto fisico e bio-molecolare cfr. M. Cocconi, *Il diritto alla tutela della salute*, Padova, 1998, pp. 37 ss. Sulle problematicità del rapporto tra diritto alla salute costituzionalmente garantito e innovazione scientifica E. Navarretta, *Diritti inviolabili e risarcimento del danno*, Torino, 1996, pp. 63 ss.; T.E. Frosini, *Tecnologie e libertà costituzionali*, in G. Comandè-G. Ponzanelli (eds.), *Scienza e diritto nel prisma del diritto comparato*, Torino, 2004, 173 ss.; A. Santosuosso, *Diritto, scienza e nuove tecnologie*, Padova, 2011.

[6] Significativo è il richiamo alla causa C-180/96 relativa alle misure adottate dalla Commissione per affrontare la prima manifestazione di encefalopatia spongiforme bovina (il cd. morbo della mucca pazza), dove la Corte in antitesi alle argomentazioni del Regno Unito aveva confermato la decisione della Commissione di limitare l'esportazione di carne bovina e dei derivati nel Regno Unito, ancorando la sua decisione non solo sul diritto derivato ma anche sul principio di proporzionalità, interpretato alla luce del principio di precauzione.

[7] In argomento, si veda A. Forti, *Il (doppio) valore della salute nel diritto alimentare (La trasformazione dei diritti sociali nel diritto comunitario)*, in *Rivista diritto agrario*, 2013, I, p. 599. Sulla centralizzazione normativa europea in tema di sicurezza alimentare cfr. L. Costato, *Principi e requisiti generali della legislazione alimentare*, in L. Costato-A. Germanò-E. Rook Basile (diretto da), *Trattato di diritto agrario*, vol. 3, Il diritto agroalimentare, Torino, 2011, p. 19.

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una delle potenziali modalità per garantire tempestivamente – in quella che è definita l'epoca della 'Quarta rivoluzione industriale'[8] – la food safety.

Nell'ambito di un quadro d'indagine certamente ampio desidero concentrare le mie riflessioni sull'importanza che l'intelligenza artificiale può avere in termini di *food safety*.

2. Il *food tech* e le innovazioni della *food safety*

L'invadenza delle nuove tecnologie nel settore alimentare, inteso in senso lato, sembra dare sprone alla formazione di una nuova area di specializzazione giuridica, ossia la *food tech law*[9]. Questa prospettiva trova fondamento nell'esigenza di valutare giuridicamente l'incidenza delle nuove tecnologie sul prodotto alimentare in una visione multilivello, si potrebbe dire "*from farm to fork*" per richiamare l'espressione di grande successo promossa dal legislatore europeo[10]. Al riguardo è possibile individuare perlomeno tre grandi filoni di indagine, che contribuiscono complessivamente alla rivisitazione del quadro giuridico della *food safety* in considerazione delle innovazioni tecnologiche.

Una prima prospettiva potrebbe essere quella gius-imprenditoriale, in considerazione del fatto che l'innovazione tecnologica e l'intelligenza artificiale invadono massicciamente la sfera della progettualità e della commercializzazione dei prodotti alimentari. Nella stessa agricoltura 4.0 l'innovazione digitale è riconosciuta come il motore di un cambiamento teso a favorire l'introduzione sul mercato di un modello di filiera corta e sostenibile, come pure di nuove proposte per ridurre gli

[8] Sul tema si rinvia al quadro delineato da A. Quarta-G. Smorto, *Diritto privato dei mercati digitali*, Le Monnier, 2020, p. 2.

[9] In argomento si veda l'interessante quadro tracciato in C. Piatti-S. Graeff Hönniger (eds.), *Food Tech Transitions Reconnecting Agri-Food, Technology and Society*, Springer, 2019.

[10] Comunicazione della Commissione '*Farm to Fork Strategy for Fair, Healthy and Environmentally-friendly Food System*' (COM/2020/381 final).

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sprechi di cibo ed innovare i processi di supply chain alimentare in grado di garantire la migliore tracciabilità alimentare[11].

Nello specifico, credo che si possano individuare una pluralità di usi concreti dell'intelligenza artificiale atti ad incidere sulla tutela dei diritti dei consumatori. Si pensi anzitutto alla progettazione di nuovi cibi dove l'uso di strumenti di intelligenza artificiale consente di poter fare affidamento su una serie di notizie ed informazioni frutto dell'uso mirato di *big data*, come ad esempio le valutazioni organolettiche e di gradimento di una determinata area geografica, sociale o generazionale di consumatori[12]. O ancora, si pensi alla progettazione di cibi arricchiti di nutrienti ritenuti potenzialmente utili per le esigenze proprie di alcune aree geografiche nonché possibile rimedio per la malnutrizione, o anche all'uso dei tanto discussi *super foods*, ossia quei cibi che hanno presunte capacità benefiche per la salute[13].

Rivolgendo poi attenzione alla sfera di interessi connessi alla conoscibilità del prodotto, anche in tal caso spiccano le potenzialità dell'intelligenza artificiale per la sua capacità di confezionare messaggi idonei a motivare all'acquisto un determinato target di consumatori anziché un altro. Il ricorso ai software di *machine learning* consente una sempre più precisa individuazione dei target di consumatori di prodotti alimentari, che sono individuati attraverso i loro interessi, l'area geografica di

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[11]Per una disamina dei vari intrecci tra agricoltura e sostenibilità si veda A. Jannarelli, *Il diritto agrario del nuovo millennio tra* food safety, food security *e* sustainable agriculture, in *Rivista di diritto agrario*, 2018, I, pp. 512 ss. Cfr. anche il documento della Commissione al Parlamento europeo, al Consiglio, al Comitato economico e sociale europeo e al Comitato delle Regioni, *Una strategia «Dal produttore al consumatore» per un sistema alimentare equo, sano e rispettoso dell'ambiente*, Bruxelles, 20 maggio 2020, COM (2020) 381 final.

[12] In argomento, L. Al-Sayed, *Technologies at the Crossroads of Food Security and Migration*, in C. Piatti-S. Graeff Hönniger (eds.), *Food Tech Transitions Reconnecting Agri-Food, Technology and Society*, cit, p. 134 dove il problema è affrontato in chiave sociale, avendo riguardo allo sviluppo della '*Food Digitalization*' e dell'*Internet of Things*'.

[13] Si tratta di un tema molto discusso nel contesto europeo e che in diverse occasioni è stato oggetto di intervento da parte della Corte di giustizia europea nel tentativo di demarcare i '*medicinal products*' rispetto ai '*botanical food supplements*' : si vedaP. Lattanzi, *Health Foods or Medicinal Products? The Botanicals Case in the European Union. A Food Law Perspective*, in AA.VV., *I diritti della terra e del mercato agroalimentare*, cit., p. 1549. Tra gli esempi discussi si colloca quello del cd. *Golden Rice*, un prodotto geneticamente modificato che è stato progettato per porre rimedio alla carenza di beta-carotene, una delle cause di cecità infantile e di gravi infermità per carenza di vitamina A; in argomento, si veda M.C. Errigo, *Diritto e OGM. Una storia complicata*, in *BioLaw Journal*, 1/2020, p. 276.

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provenienze e, non da ultimo, le ricerche attinenti all'alimentazione che hanno precedentemente svolto nel web. Il consenso dato dall'utente della rete alla raccolta dei cookies permette l'analisi in forma anonima ed aggregata di una serie di dati connessi alla sua persona (con i limiti dell'art. 22 del Reg. UE 2016/679)[14], attraverso i quali le società di marketing e comunicazione possono realizzare efficacemente gli obiettivi imprenditoriali che fanno capo al singolo prodotto, ossia la sua diffusione nel mercato possibilmente accaparrando la fiducia precedentemente riposta in prodotti simili[15].

In linea con le valutazioni connesse all'uso dell'intelligenza artificiale nel quadro delle attività collegate alla pubblicità ed alla diffusione di un prodotto nel mercato c'è anche la considerazione dello strumento che per eccellenza è destinato alla informazione del prodotto alimentare, vale a dire l'etichetta. Ovviamente la riflessione è rivolta non all'etichetta cartacea ma più nello specifico all'etichetta letta e/o interpretata tramite l'uso di smartphone ed app che attraverso un QCODE decodificano le informazioni nutrizionali del prodotto alimentare sul profilo del singolo consumatore. La lettura di informazioni nutrizionali sulla base dei dati personali (quali il peso, l'età, il fabbisogno calorico, i problemi di salute o le intolleranze) di cui dispone il device stesso lasciano aperto l'interrogativo dell'impatto di tali evoluzioni sulla privacy dei consumatori e sulla effettiva tutela della riservatezza della sua sfera più intima.

Venendo alla seconda delle tre prospettive della *tech food law* di cui voglio fare menzione, ossia quella gius-pubblicistica, emergono alcune potenzialità dell'intelligenza artificiale che possono realizzare in modo precipuo obiettivi di *food*

[14] In relazione al diritto riconosciuto in capo all'individuo di non essere sottoposto a trattamenti interamente automatizzati capaci di incidere significativamente sulla sua persona.

[15] Il tema riguarda anche il c.d. *italian sounding* (su cui I. Carreño-P. R. Vergano, *Geographical indications, "Food Fraud" and the Fight Against "Italian sounding" Products*, in *European Journal of Risk Regulation*, 7, 2016, pp. 416 e ss.) ed eventualmente le pratiche sleali commesse nel tentativo delle aziende di accaparrarsi le risorse di fiducia accumulate dai consumatori nei prodotti di altre aziende (in argomento si rinvia a F. Montanari-C. Varallo-D. Pisanello, *Food Fraud in the EU*, in *European Journal of Risk Regulation*, 7/2016, p. 197 ss.; B. van der Meulen, *Is Current EU Food Safety Law Geared up for Fighting Food Fraud?*, in *Journal für Verbraucherschutz und Lebensmittelsicherheit*, 2015, f. 10 (Suppl. 1), p. 19 ss).

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safety a livello sovranazionale[16], non solo in relazione alla tutela della salute dei consumatori ma anche in termini di sostenibilità della produzione alimentare e delle esigenze connesse alla economia circolare. Invero, l'applicazione dell'intelligenza artificiale al settore alimentare può consentire anzitutto il monitoraggio dello standard europeo di sicurezza alimentare in relazione all'incidenza di batteri o cibi contaminati (come ad esempio la salmonellosi) o di patologie anomale (come quella della encefalopatia spongiforme bovina), quindi di incidere maggiormente sulla tutela del diritto alla salute del consumatore e sul principio di precauzione (art. 14 Reg 172/2002), limitando nell'uno e nell'altro caso i problemi connessi alla *food unsafety*[17].

Sempre in una prospettiva di garanzia dei diritti fondamentali della persona, dove il diritto alla salute è chiamato a contemperarsi con nuovi paradigmi, come quelli degli obblighi intergenerazionali e della salvaguardia dell'ambiente e delle risorse comuni, il ricorso a strumenti di intelligenza artificiale può contribuire alla limitazione della cd. *food waste*[18]. Non solo: il contenimento degli sprechi della catena alimentare

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[16] La Corte di Giustizia ha rimarcato in più occasioni come a fronte di un quadro europeo della *food safety*, che appare sempre più armonico tra i contesti nazionali di riferimento, esista un potere discrezionale degli Stati membri relativo al livello in cui intendono tutelare la salute pubblica. Di questa interpretazione che muove dall'art. 6 del TFUE, e quindi dalla qualifica come 'materia complementare' della tutela e del miglioramento della salute rispetto alle normative nazionali, si trova un interessante chiave di lettura nella sentenza del 19 gennaio 2017, causa C-282/15, Quisser Pharma (su cui si menziona la nota di L. Uccello Barretta, *La sicurezza alimentare tra Unione europea e regimi nazionali. Brevi notazioni su una recente pronunzia della Corte di Giustizia*, in DPCE on line, 2/2017, pp. 391 ss.).

[17] A fronte di una popolazione globale che nel 2050 supererà la soglia di 9 miliardi di persone, il problema della *food unsafety* coinvolge inevitabilmente quello della *food insecurity* (sulla prospettiva stessa cfr. L. Scaffardi, Novel Food, *una sfida ancora aperta tra sicurezza alimentare, innovazione e sviluppo sostenibile*, in L. Scaffardi-Z. Zeno-Zencovich, *Il cibo e il diritto. Una prospettiva comparata*, II, Roma3Press, 2020, pp. 735 e ss). La valutazione della *food unsafety* tramite strumenti di intelligenza artificiale risente ovviamente del modello giuridico di riferimento e del triplice passaggio dal linguaggio naturale (rappresentativo della realtà) verso quello tecnico-giuridico (rappresentativo della realtà e del fenomeno giuridico) e poi ancora verso quello formalizzato attraverso elaboratori elettronici. Come dire che il sistema di *food unsafety* risente del rapporto tra 'sistemi giuridici' e 'sistemi di intelligenza artificiale' (sul rapporto stesso cfr. A. Cantaldo-F. Campara, *Intelligenza artificiale e diritto. Dai sistemi esperti "classici" ai sistemi esperti "evoluti"*, in G. Taddei Elmi-A. Contaldo, *Intelligenza artificiale. Algoritmi giuridi*ci, ius condendum *o "fantadiritto"?*, Pacini Giuridica, 2020, p. 71).

[18] La dottrina parla al riguardo di '*Bio-intelligent Transition*': si veda S. Graeff Hönniger -F. Khajehei, *The Demand for Superfoods: Consumers' Desire, Production Viability and Bio-intelligent Transition*, in C. Piatti-S. Graeff Hönniger (eds.), *Food Tech Transitions Reconnecting Agri-Food, Technology and Society*, *cit*., p. 90.

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consentono di monitorare la produzione e l'allocazione delle risorse alimentari secondo best practices, nella duplice prospettiva di una maggiore democrazia della *food security* e di una crescente attenzione verso le esigenze di un'economia circolare, la cui base giuridica si ravvisa nel modello economico richiamato nell'art. 3, primo e quinto comma, del Trattato di Lisbona del 2007 e su alcuni strumenti di *soft law*[19].

Una terza prospettiva di incidenza della intelligenza artificiale sulla *food law*, che è direttamente interconnessa con quelle menzionate precedentemente, è quella gius-consumeristica. Al centro della riflessione si trova il consumatore e la vulnerabilità giuridica dei suoi diritti attraverso strumenti di intelligenza artificiale. Invero la figura consumatore è coinvolta sotto molteplici punti di vista che incidono sulla sua libertà contrattuale, sulla corretta informazione, sul diritto all'autodeterminazione attraverso le scelte alimentari e, non da ultimo, sull'uso dei suoi dati conformemente al Reg. EU 2016/679. Per avere contezza di come il tema 'alimentazione' venga lentamente scardinato dalla convenzionale alternativa in cui si concretizzava precedentemente (pasto in casa / pasto al ristorante), è sufficiente rivolgere attenzione ai trend emersi nell'ultimo anno, quando la pandemia e le limitazioni dei movimenti hanno fatto sì che le piattaforme di *food delivery* diventassero improvvisamente un servizio non 'utile' ma 'essenziale' per la vita di molte persone.

L'innovazione tecnologica e l'uso di strumenti di intelligenza artificiale invadono il campo e le regole del contratto di acquisto di prodotti alimentari o di pasti pronti, che tende ad essere realizzato attraverso piattaforme di e-commerce con consegna diretta da parte del venditore o anche attraverso *food delivery*. Più a monte si colloca l'incidenza anch'essa importante delle scelte alimentari del consumatore: è nota la diffusione sociale di programmi alimentari dietetici o terapeutici a cui il consumatore si affida attraverso l'uso delle cosiddette *healthy eating apps*[20]. La relazione giuridica si colloca

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[19] Comunicazione della Commissione europea '*Verso un'economia circolare: programma per un'Europa a zero rifiuti*' (COM, 2014, 398).

[20] Grazie all'uso di algoritmi di valutazione e classificazione dei prodotti alimentari, sono state diffuse app che leggono l'etichetta di un determinato prodotto alimentare o ne decifrano per il consumatore i contenuti in relazione alle sue esigenze nutrizionali (si pensi ad esempio a MyFitnessPal, HealthyOut, Noom, OptUp, Rise e Edo), offrendo una lettura 'assistita' dell'etichetta alimentare (attraverso la sola scansionare del codice a barre con la fotocamera dello smartphone). In argomento sia consentito il rinvio a S. Lanni-G. Magri, *Healthy Eating Apps: la salubrità degli alimenti in mano agli algoritmi*, in *Osservatorio di diritto civile e commerciale*, 1/2020, pp. 77-104.

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nell'ambito di quanto rientra nella responsabilità delle piattaforme digitali, evocando però profili tipici della responsabilità professionale nel caso in un cui nel backstage siano presenti nutrizionisti, come del resto potrebbe dedursi dalla configurazione delle apps stesse che non di rado sono pubblicizzate come '*a nutritionist in your pocket*'[21].

Last but not least, sempre nell'ambito delle problematiche giu-consumeristiche sembra cruciale l'esempio in cui il consumatore decida di delegare in toto tutto ciò che riguarda l'alimentazione (dall'acquisto alla preparazione del cibo, dalla valutazione nutrizionale alla scelta del menù) ad una piattaforma con cui sia possibile concludere un contratto di somministrazione. L'esperimento è riuscito ad un imprenditore italiano che ha creato una start-up "Feat-Food" dove puntando sugli algoritmi e sul machine learning si impara a conoscere gli utenti, non solo attraverso i dati da loro forniti ma anche sfruttando aggiornamenti di profilo e dati aggregati di tutti gli iscritti alla piattaforma stessa, al fine di gestire letteralmente tutta l'alimentazione giornaliera dalla A alla Z degli utenti che ricevono a casa propria i pasti, anche per tutta la settimana[22].

Orbene, se le 3 prospettive menzionate danno conto di come i *big data* ed i sistemi di intelligenza artificiale stiano invadendo diverse prospettive della *food law*, tanto da parlare di *food tech law*, la domanda che mi pongo come giurista è 'se' e, quindi, 'come' la *food safety* possa essere migliorata dall'intelligenza artificiale. In altre parole, l'intelligenza artificiale e l'apprendimento automatico possono trasformare e migliorare la *food safety*? Quali i modelli giuridici di riferimento?

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[21] In senso scettico, J. Chen-W. Berkman-M. Bardouh et al., *The Use of a Food Logging App in the Naturalistic Setting Fails to Provide Accurate Measurements of Nutrients and Poses Usability Challenges,* in *Nutrition*, 2019, pp. 208-216 dove con attenzione specifica ad una delle apps più usate (MyFitnessPal) sottolineano come «*food omissions and the large underestimation of nutrients […] reinforces the importance of health professionals*».

[22] Alla sempre più stretta correlazione tra '*data protection*' e '*consumer protection*' (su cui cfr. N. Helberger-B.F. Zuiderveen-A. Reyna, *The Perfect Match? A Closer Look at the Relationship between EU Consumer Law and Data Protection Law*, in *Common Market Law Review*, 54, 2017, p. 1427) sono ricollegati molteplici effetti. Si è ad esempio rivolta attenzione all'incidenza delle nuove tecnologie, non tanto sulle scelte e sul comportamento finale dei consumatori, quanto piuttosto sui processi psicologici di ordine superiore che sono proiettati, inconsapevolmente, ad una riduzione della percezione dell'importanza da parte dei consumatori stessi di esercitare un controllo vigile ed attento sulle scelte da porre in essere (su cui cfr. Q. André-Z. Carmon-K. Wertenbroch et alii, *Consumer Choice and Autonomy in the Age of Artificial Intelligence*, in *Customer Needs and Solutions*, 5, 2018, pp. 28-37).

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3. *Newly developed foods* e nuovi problemi

All'incontro dell'International Association for Food Protection del 2019 Frank Yiannas, vice commissario per la food policy presso la USA Food and Drug Administration (FDA), ha elogiato l'intelligenza artificiale come uno degli strumenti più incoraggianti per la futura realizzazione della *food safety*, avendo riguardo sia alle esigenze propriamente interne del mercato americano (ad esempio, la sorveglianza dei patogeni di origine alimentare) sia alle esigenze più impellenti nel mercato transnazionale di prodotti alimentari (tra le quali, la sicurezza e la tracciabilità dei prodotti importati)[23].

L'obiettivo stesso della *food safety*, così come reso noto dalla circolazione del modello europeo di riferimento, ha esercitato una certa qual influenza sulle regole del mercato alimentare americano, proiettando la salubrità del prodotto alimentare al centro di una rinnovata attenzione scientifica. Invero, da alcuni anni emerge un avvicinamento tra il modello USA e quello EU di *food safety* avendo riguardo al diritto sostanziale così come all'esercizio delle potestà pubblicistiche ad esso inerenti. Mentre nell'esperienza europea l'alimento è considerato sicuro fino a prova contraria, grazie ad una serie di scrupolosi controlli, che sono effettuati in relazione all'osservanza degli standard di qualità prima della immissione del prodotto nel mercato, come pure grazie alla significativa possibilità di poter tracciare l'alimento durante tutta la filiera agro-alimentare, diversamente nell'esperienza statunitense, perlomeno fino alla attribuzione in seno alla FDA di alcune funzioni che sono tipiche dell'EFSA soprattutto in termini di 'prevenzione', è stato lungamente predominante un approccio giuridico ex post, vale a dire connesso alla eventuale e fortuita emersione di problemi e rischi per la salute dei consumatori[24].

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[23] La FDA ha annunciato un programma pilota per utilizzare l'intelligenza artificiale per contribuire a garantire la sicurezza alimentare degli alimenti importati (www.fda.gov/news-events/press-announcements/statement-acting-fda-commissioner-ned-sharpless-md-and-deputy-commissioner-frank-yiannas-steps-usher).

[24] L'avvicinamento tra EU e USA in relazione alla *food safety* viene ancorato al *Food Safety Modernization Act* del 2011, che ha innovato il *Federal Food, Drug and Cosmetic Act* del 1938 predisponendo parametri di valutazione (come quello della «reasonable probability» della nocività di un prodotto alimentare per la salute umana) e, allo stesso tempo, promuovendo strumenti di tracciabilità dei prodotti alimentari (come quello del sistema HACCP). Per un quadro di riferimento si vedano M. Vinay-D. Maurizi, *La redazione de*l Food Safety Plan, EPS, 2017.

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L'avvicinamento summenzionato oltrepassa l'armonizzazione tra regole ed organismi istituzionali deputati alla loro attuazione. L'esigenza di tutelare la salute dei consumatori come obiettivo globale e l'esigenza di limitare vincoli non doganali alla commercializzazione internazionale di prodotti alimentari stanno spronando, tanto in Europa quanto negli Stati Uniti, l'uso e la fiducia verso una *food safety* da conseguire attraverso l'intervento dell'intelligenza artificiale. Sebbene l'attenzione dei giuristi sia spesso orientata dai progressi realizzati dal machine learning per rilevare e prevedere il rischio alimentare (anche sulla base dei *big data*), non da meno emerge la consapevolezza sulla inadeguatezza della prospettiva stessa allorquando non sia inserita nel quadro delle potenzialità offerte dalle nuove tecnologie. Come dire che al fine di favorire l'applicazione delle più recenti conoscenze tecnologiche alla produzione di ingredienti ed alimenti sicuri, il giurista è chiamato a prendere in considerazione le scoperte connesse al campo della *food safety* a livello globale.

In primo luogo, l'intelligenza artificiale applicata alla *food safety* deve rivolgere preliminare attenzione non solo alle forme di automazione dei processi che possono, ad esempio, migliorare la tracciabilità dei prodotti alimentari (come i sistemi di tracciabilità e rintracciabilità che utilizzano tag RFID, codici QR, archiviazione di dati cloud, blockchain)[25] ma anche alla cd. testing technology[26]. Ad esempio la tecnologia LAMP (Loop-mediated isothermal AMplification) che è utilizzata, tre le altre cose, nella certificazione genetica in ambito agroalimentare e nel controllo dei patogeni in grado di colpire persone con deficit del sistema immunitario, e che dal punto di vista delle esigenze del commercio internazionale può contribuire a limitare ulteriormente le diversità di approccio tra USA e UE, come pure può favorire una maggiore consumer confidence nel cibo che viaggia tra le due sponde dell'oceano[27].

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[25] Con attenzione alle tecniche di miglioramento della tracciabilità alimentare cfr. H. Kim-M. Laskowski, *Agriculture on the Blockchain: Sustainable Solutions for Food, Farmers and Financing*, in D. Tapscott (ed.), *Supply Chain Revolution*, BarrowBooks, 2018, open access; J. Lin-Z. Shen-A. Zhang-Y Chai, *Blockchain and IoT based Food Traceability for Smart Agriculture*, in *Proceedings of the 3rd international Conference on Crowd Science and Engineering*, 2018, pp. 1-6.

[26] Cfr. https://www.food-safety.com/articles/6416-artificial-intelligence-and-food-safety-hype-vs-reality

[27] Fatta salva la distinzione tra «trust and belief about trustworthiness» che è puntualmente sottolineata da A.L. Macready-S. Hieke-M. Klimczul-kochanska et alii, *Consumer Trust in the Food Value Chain and its Impact on Consumer*

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Nondimeno, l'uso dell'intelligenza artificiale per rafforzare una *global food safety* richiama una significativa attenzione verso la creazione e/o la diffusione dei cd. *newly developed foods*, per riprendere la terminologia adoperata dal legislatore europeo nel Reg EU 2283/2015, in modo particolare in riferimento all'art. 3, comma 2 lett. a)[28]. Invero, la scienza già ha dimostrato come attraverso l'intelligenza artificiale sia possibile proporre formule alimentari senza l'uso di derivati animali, come pure coltivazioni agricole con limitato impatto ambientale e, non da ultimo, nuove piante dall'editing genetico teso ad accentuare alcune caratteristiche di resilienza rispetto a quella abituale. Naturalmente i problemi di regolazione sono molteplici e solo in via di primo approccio normativo sono configurabili in una categoria sistematica onnicomprensiva (come quella dei *newly developed foods* del Reg EU 2283/2015), poiché il valore dogmatico che presenta l'adozione di cibi tradizionali già utilizzati in Paesi terzi (e quindi nuovi solo per il mercato europeo) assume una portata ovviamente diversa da quella dei cibi che sono frutto di clonazione o risultato finale di tecniche di bio-ingegneria (e quindi nuovi in quanto esito di recenti ricerche scientifiche)[29].

I *newly developed foods* sono estremamente importanti per modernizzare il sistema di food safety in considerazione delle innovazioni che tra non molto potrebbero bussare alla porta del mercato europeo, non solo in termini di innovazione scientifica

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Confidence: A Model for Assessing Consumer Trust and Evidence from a 5-Country Study in Europe, in *Food Policy*, 92, 2000, open access.

[28] L'articolo 3, punto 2, lett. a) nel quadro di un approccio definitorio, elenca minuziosamente quelli che sono considerabili come 'nuovi alimenti', tra i quali rientrano espressamente, per gli interessi specifici del tema affrontato in questo lavoro, «gli alimenti risultanti da un nuovo processo di produzione non usato nella produzione di alimenti nell'Unione Europea prima del 15 maggio 1997» (VII) e «gli alimenti costituiti da nanomateriali ingegnerizzati» (VIII).

[29] La peculiarità della categoria è nota al legislatore europeo, che oltre a richiamare la necessità di «normative specifiche per gli alimenti derivati da animali clonati» sottolinea l'opportunità di «un'etichettatura adeguata al consumatore finale» (cfr. considerando 14 del Reg. EU 228372015). Questi cibi coinvolgono inevitabilmente il consumatore ed il suo diritto ad una informazione esauriente e corretta, da qui l'esigenza di un intervento specifico da parte del legislatore europeo che consenta un rinnovato dialogo con i principi basilari degli ordinamenti giuridici nazionali, non da ultimo quelli degli artt. 9 e 33 della costituzione italiana (cfr. L. Scaffardi, Novel Food, *una sfida ancora aperta tra sicurezza alimentare, innovazione e sviluppo sostenibile*, cit., pp. 772).

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(penso alla carne sintetica o a quella elaborata con stampanti 3D)[30] ma anche in termini di trasformazioni genetiche (si pensi alle sperimentazioni genetiche sugli animali, come quelle che attraverso geni di vegetali cercano di abbattere la presenza di grassi e, quindi, limitare alcuni danni alla salute umana, come quelli causati da iper-colesterolemia)[31]. In entrambi i casi si registrano questioni giuridiche di ampia portata che richiamano l'eticità della ricerca scientifica e, non da ultimo, la dignità delle creature viventi, come si coglie nei testi costituzionali di molti Paesi e, non da ultimo, nell'art. 13 del Trattato di Lisbona[32].

Le innovazioni summenzionate, frutto dell'applicazione di strumenti di intelligenza artificiale alla produzione ed alla commercializzazione di prodotti alimentari, richiamano una valutazione secondo la lente del giurista sugli aspetti positivi e, peraltro, anche sugli aspetti problematici della interazione tra intelligenza artificiale e *food safety*.

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[30] Singapore è stato il primo Paese al mondo ad approvare la vendita di carne di pollo creata in laboratorio (https://www.greenme.it/mangiare/altri-alimenti/carne-laboratorio-singapore/). Per una riflessione su questi temi cfr. A. Seehafer, *Meat 2.0. The Regulatory Environment of Plant-based and Cultured Meat*, in *European Food and Feed Law Review*, 14, 2019, pp. 323-331; I. Skartsaris-C. Piatti, *Altering Production Patterns in the Food Industry: 3D Food Printing*, in C. Piatti-S. Graeff Hönniger (eds.), *Food Tech Transitions Reconnecting Agri-Food, Technology and Society*, cit, pp. 97 e ss.

[31] Nel 2002 ricercatori giapponesi hanno sperimentato la creazione di un maiale con sistema genetico mutato attraverso l'uso di un gene dello spinacio, diminuendo del 20% la presenza di grassi saturi al fine di poter abbattere il colesterolo nelle popolazioni che fanno uso prevalente di quella carne. Al di là della presenza di problemi di natura etica (su cui cfr. D.L. Burk, *Dolly and Alice*, in *Journal of Law and the Biosciences*, 2, 2015, pp. 606-626), appare necessario avere considerazione anche dei problemi connessi alla eventuale circolazione del prodotto nel mercato europeo, o meglio della corretta informazione del prodotto stesso per tutti i consumatori europei (invero, solo pochi Stati europei prevedono attualmente un'etichettatura 'GM-free' sull'esempio di quella promossa a partire dal 2009 nel mercato tedesco). Problema ulteriore è quello del commercio UE-USA, in quanto diversamente dall'esperienza EU (Dir. CE 18/2001 e Reg. 1830/2003) negli USA non è richiesta un'etichettatura specifica per la maggior parte di cibi che prevedono organismi geneticamente modificati (FDA, 1992 Policy n. 37, 22, 991). In riferimento al problema dell'etichettatura OGM nel contesto EU-USA cfr. A. Rosso Grossmann, *Labels for Genetically Modified Foods: A Debate in the United States*, in AA.VV., *I diritti della terra e del mercato agroalimentare*, cit., p. 1403 ss.

[32] Cfr. art. 80 cost./Svizzera, art. 20 cost./Germania, art. 11, comma 8 cost./Austria. Per un approfondimento si fa rinvio a C. Casonato, *Diritto costituzionale comparato e scienze della vita: paradigmi e connessioni*, in DPCE on line, 1/2018, p. 5 e F. Rescigno, *I diritti animali nella prospettiva contemporanea: l'antispecismo giuridico e la soggettività animale*, in L. Scaffardi-Z. Zeno-Zencovich, *Il cibo e il diritto. Una prospettiva comparata*, cit, p. 850.

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4. Le interazioni tra intelligenza artificiale e *food safety* nella lente del giurista

La sorveglianza delle attività degli utenti della rete e la rielaborazione dei loro dati per finalità non sempre controllabili hanno consentito di parlare già in altra occasione di un *dataquake*[33]. Il giurista guarda a questo fenomeno attraverso il filtro dei valori, principi e paradigmi del proprio sistema giuridico di riferimento, e cerca di arginare l'invasione tramite strumenti di intelligenza artificiale dei diritti del consumatore, o meglio la vulnerabilità degli stessi.

Avendo riguardo agli aspetti problematici che si collocano nel crocevia tra *food law* e *consumer law*, dove l'invadenza dell'intelligenza artificiale altera gli equilibri finora raggiunti, appare anzitutto necessario rivolgere una specifica attenzione non solo alle diverse ricadute socio-culturali connesse all'uso dei *big data*, ma anche all'utilizzazione degli stessi fatta per realizzare una marcata ingerenza sulle scelte alimentari dei consumatori attraverso il cd. data mining[34]. In modo parallelo, il neuromarketing e le neuroscienze applicate ai prodotti alimentari sono un'altra prospettiva da avere sotto controllo. Partendo dal presupposto che la sfera emozionale prevale sulla sfera cognitiva ogni volta che il consumatore deve prendere una decisione, l'applicazione al marketing delle tecniche neuroscientifiche permette in termini predittivi una

[33] Sia consentito il rinvio S. Lanni, Dataquake*: intelligenza artificiale e discriminazione del consumatore*, in *Nuovo Diritto Civile*, 2/2020, pp. 97-123.

[34] Il c.d. *data mining* con cui si determina la profilazione degli utenti appare avulso dalle regole del consenso da parte del consumatore. Il problema dal punto di vista giuridico non si ravvisa tanto nella profilazione stessa quanto nel fatto che l'attività di classificazione da cui essa muove è scollegata dalla volontà dell'individuo e sottratta a qualsiasi forma di controllo collettivo (così B. Saetta, *Algoritmi, intelligenza artificiale, profilazione dei dati: cosa rischiamo davvero come cittadini?*, in https://www.valigiablu.it/algoritmi-dati-rischi/). Non da meno la dieta alimentare tende a divenire uniforme e, parallelamente, le scelte connesse al consumo di prodotti alimentari sono sempre più frequentemente standardizzate, con pericoloso riflesso in termini di assimilazione nonché di impoverimento culturale (S. Tommasi, *Food Diversity and Consumer Protection*, in *European Food and Feed Law Review*, 12, 2017, p. 217).

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migliore comprensione di ciò che determina le scelte dei consumatori a livello cerebrale e quindi anche una sua 'influenzabilità[35].

Emerge sotto diversi profili un'accentuazione della vulnerabilità del consumatore rispetto al mercato, che è legata alle sue libertà ed al suo potere di autodeterminazione, ma che presenta anche problemi di risvolto culturale soprattutto in termini di discriminazione basata sulla nazionalità (artt. 18 e 19 del Trattato di funzionamento dell'UE), o sulla parità di trattamento fra le persone, indipendentemente dalla razza e dall'origine etnica (Dir. CE 43/2000) o anche sui blocchi geografici ingiustificati (Reg. UE 2018/302)[36]. La violazione di questi diritti insieme alla violazione della *food safety* attraverso l'uso di strumenti elettronici intelligenti apre le porte allo spinoso dilemma della responsabilità civile, o meglio all'applicazione della Dir. CEE 374/1985 (poi modificata dalla Dir. CEE 34/1999) relativa alla responsabilità da prodotto difettoso.

I profili critici per sussumere validamente nella disciplina summenzionata gli attuali e futuri strumenti di intelligenza artificiale sono molteplici, non solo perché non si tratta di prodotti statici bensì capaci di adattamento ed apprendimento ma anche perché la loro struttura non è in linea con quanto emerge dall'art. 2 della Dir. CE 374/1985[37]. Né in relazione al tipo di responsabilità credo possa richiamarsi tout court il principio della *culpa in vigilando*, secondo i parametri delineati dal legislatore italiano

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[35] Si pensi ad esempio al cd. *egg-biofeedback* avendo riguardo all'indice della memoria, o all'attenzione focalizzata che permette di concentrarsi su uno stimolo rilevante, nonché all'indice evocativo dei consumatori (F. Gallucci, *Marketing emozionale e neuroscienze*, Milano, 2011).

[36] In relazione alla garanzia e alla tutela dei diritti dei consumatori, è stato sottolineato come l'analisi e la valutazione degli effetti indiretti dei *big data* rimarchino la presenza di pregiudizi, avendo in considerazione sia le alternative operate dagli sviluppatori dei software di riferimento, sia i processi di autoapprendimento attraverso i quali si consolidano i risultati delle scelte finali operate dai consumatori mediante i motori di ricerca. A questo proposito si trovano utili riferimenti nel Reg. UE 679/2016, dove si fornisce la disciplina di un sistema preliminare per la protezione dei dati oggetto di un sistema decisionale automatizzato, ma anche la disponibilità di strumenti idonei a verificarne l'attendibilità, quali ad esempio sistemi di *audit* per gli algoritmi e di certificazioni per gli sviluppatori (in argomento, F. Pizzetti, *Intelligenza artificiale, protezione dei dati personali e regolazione*, Torino, 2018, pp. 46 e ss.).

[37] In argomento A. Baldi, D. Mula, *Responsabilità civile e intelligenza artificiale*, in G. Taddei Elmi, A. Contaldo (eds.), *Intelligenza artificiale. Algoritmi giuridici,* ius condendum *o "fantadiritto"?*, cit., p. 182-183. Con attenzione ai caratteri antropocentrici e responsabili dell'intelligenza artificiale si vedano le *Proposte per una strategia italiana per l'Intelligenza Artificiale* elaborate dal Gruppo di Esperti MISE e le relative Raccomandazioni pp. 87 e ss.

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attraverso gli artt. 2049 e 2051 del codice civile. È chiaro che una tale colpa sia stata storicamente ancorata al parametro della diligenza e della perizia, e quindi diremo, alla possibile prevedibilità del danno; viceversa, nel contesto casistico di nostro interesse, è dimostrato ampiamente come gli strumenti dotati di *machine learning* possano esulare da forme di controllo, per la loro capacità di autoapprendimento attraverso la rielaborazione di dati ed informazioni. In presenza di tali problemi di opacità, quantomeno la responsabilità di riferimento dovrebbe inquadrarsi in un più ampio contesto di responsabilità solidale (proprietario-utente-produttore) a meno che non si riesca a provare la violazione di un obbligo di verifica delle modalità con cui l'algoritmo elabora i dati[38].

Non da ultimo, tra le criticità colte fa capolino l'esigenza di un uso etico dell'intelligenza artificiale, che possa fondarsi su un approccio dove le esigenze di 'innovazione' e quelle di 'regolazione' siano bilanciate in ottemperanza dei valori e dei paradigmi socio-giuridici da cui muove il modello europeo di *food law*[39]. Ciò equivale a dire che la sicurezza alimentare e l'inclusione sociale sono obiettivi che godono di pari dignità rispetto a quelli propri del mercato e dell'economia. Gli obiettivi di *food safety* e quelli di *food secutity* sono entrambi al centro delle discussioni scientifiche che muovono dalla crisi alimentare mondiale e dal suo contenimento attraverso un uso etico dell'intelligenza artificiale[40].

A fronte delle criticità finora evidenziate emergono tuttavia diversi elementi positivi, che suggeriscono dal punto di vista dei dati scientifici come il ricorso a

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[38] Problema parallelo è quello della possibilità di considerare l'algoritmo o il sofware come prodotti o componenti di un prodotto ai sensi dell'art. 114 del codice di consumo italiano (cfr. R. Montinaro, *Responsabilità da prodotto difettoso e tecnologie digitali tra* soft law *e* hard law, in *Persona e Mercato*, 4/2020, p. 354).

[39] Significativo appare il richiamo agli '*Orientamenti etici per un'AI affidabile*', pubblicato nel 2019 dal Gruppo europeo di alto livello sull'intelligenza artificiale, dove si sottolinea la necessità di poter fare riferimento a tre componenti essenziali, vale a dire: a) la legalità, poiché l'AI deve essere in grado di poter di ottemperare a tutte le norme giuridiche applicabili; b) l'eticità, in quanto l'AI deve poter assicurare un riscontro dei principi e dei valori etici; c) la robustezza, dal punto di vista tecnico e sociale, al fine di prevenire i danni che gli strumenti di intelligenza artificiale possono causare. In argomento, G. Comandè, *Unfolding the Legal Component of Trustworthy AI: A Must to Avoid Ethics Washing*, in *Annuario di diritto comparato e studi legislativi*, 2020, p. 41.

[40] Il tema è stato al centro di una conferenza internazionale "*AI, Food for All*"; cfr. https://www.vaticannews.va/it/mondo/news/2020-09/accademia-vita-paglia-intelligenza-artificiale-call-fame-ibm-fao.html.

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strumenti di intelligenza artificiale possa contribuire a rafforzare la sicurezza alimentare e la fiducia dei consumatori nel mercato (un «ecosistema di fiducia»[41]), come pure possa contribuire alla realizzazione della salvaguardia dell'ambiente, sia in termini di scelte alimentari sostenibili sia in termini di equilibrio ed allocazione della produzione.

L'obiettivo che si manifesta come precipuo è quello della sorveglianza, in termini di contributo alla preservazione della salute dei consumatori e della sicurezza del mercato alimentare. Negli USA è stato stimato che solo uno ogni trenta casi di salmonella non tifoide sia rilevato attraverso strumenti di laboratorio. Una delle più grandi speranze è che l'uso dell'intelligenza artificiale possa favorire la diagnosi e la sorveglianza delle malattie di origine alimentare. Si tratta di un obiettivo che rientra nei desiderata fatti propri dal legislatore europeo nella Risoluzione del Parlamento europeo del 12 febbraio 2019 su una politica europea globale in materia di robotica e intelligenza artificiale (art. 3.1.5 «agricoltura e catena alimentare»).

Proprio a quest'ultimo proposito ciò che riceve un'enorme attenzione è l'uso dell'intelligenza artificiale per tutelare ex ante la *food safety* attraverso l'uso di flussi di dati finora non utilizzati, come ad esempio quelli offerti da social network (Twitter, Facebook etc.) o nello specifico da piattaforme digitali considerate un punto di riferimento in tema di cibo e/o ristorazione (quali, ad esempio, Trip-advisor o Yelp). Queste piattaforme possono determinare indirettamente una recrudescenza di disparità di trattamento, attraverso la raccolta di dati che in forma aggregata sono potenzialmente in grado di innescare meccanismi di discriminazione in violazione degli obiettivi richiamati dal considerando 71 del Reg. EU 679/2016[42] e, ancor prima, di quanto faticosamente garantito attraverso l'art. 3 della costituzione italiana[43].

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[41] Così: Commissione europea, *Libro bianco sull'intelligenza artificiale – Un approccio europeo all'eccellenza e alla fiducia*, COM (2020) 65, 3.

[42] Nella lettura del considerando richiamato nel testo la dottrina individua il «principio di non discriminazione algoritmica»; A. Simoncini, *Diritto costituzionale e decisioni algoritmiche*, in S. Dorigo, *Il ragionamento giuridico nell'era dell'intelligenza artificiale*, Pacini Giuridica, 2020, p. 59.

[43] In argomento F. Z. Borgesius (ed.), *Discrimination, Artificial Intelligence, and Algorithmic Decision-making*, Council of Europe, Strasbourg, 2018, 18 ss.; L. Giacomelli, Big brother is «gendering» you. *Il diritto antidiscriminatorio alla prova dell'intelligenza artificiale: quale tutela per il corpo digitale?*, in *Biolaw Journal*, 2/2019, pp. 278 ss.; G. Resta,

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Proprio in tema di *food safety* è stato segnalato come l'utilizzo di termini quali 'malato', 'vomito' o 'intossicazione alimentare' sia stato utilizzato in alcuni contesti degli Stati Uniti per estrapolare degli alert finalizzati a prevenire la diffusione di rischi alla salute da contaminazione alimentare, favorendo in tal modo la creazione (o il rafforzamento) di una 'società della sorveglianza'[44]. Nell'ottica del legislatore europeo verrebbero però in questo modo ad essere violati lo spirito e la lettera del Reg. UE 679/2016, poiché la protezione dei dati occupa una posizione cruciale da cui non è possibile prescindere non solo perché base dello sviluppo e della realizzazione personale ma anche perché fattore e supporto di altri diritti fondamentali, che attraverso la lettura della *data protection* stessa non corrono il rischio di essere svuotati di contenuto per la persona che fa ingresso nell'ecosistema digitale[45].

Riguardo alla salvaguardia dell'ambiente summenzionata, si tratta non solo di ridurre la cosiddetta *food waste*, che già di per sé negli ultimi anni è stata ampiamente richiamata come obiettivo da documenti programmatici dell'UE e delle principali

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Governare l'innovazione tecnologica: decisioni algoritmiche, diritti digitali e principio di uguaglianza, in *Politica del diritto*, 2/2019, p. 218.

[44] Già i dipartimenti sanitari di Boston, Chicago, Las Vegas, New York City e St. Louis hanno sperimentato sistemi di sorveglianza di questo genere, utilizzando Twitter, Yelp e dati sulle chiamate registrate verso i numeri di pronto soccorso; è stato creato un sistema per estrarre un allarme dai post caricati dagli utenti delle piattaforme digitali, al fine di identificare potenziali problemi di sicurezza alimentare; tuttavia affiancando parole come 'vietnamita' e 'cinese' i dati sono stati utilizzati anche per scovare le ristorazioni sporche, viceversa affiancando parole come 'belga' ed 'europeo' i parametri sono stati orientati verso ristorazioni in linea con gli standard igienici (cfr. https://www.food-safety.com/articles/6416-artificial-intelligence-and-food-safety-hype-vs-reality). Questa prospettiva mostra chiaramente come la disciplina della raccolta e del trattamento dei dati stessi non basti per tutelare compiutamente il consumatore dall'incidenza fuorviante degli algoritmi nei contesti mediati dalla tecnologia. Invero, è necessario rivolgere una maggiore attenzione anche alle diverse ricadute socio-culturali connesse all'uso dei *big data*: si è in presenza di un *dataquake* accentuato dall'aggregazione di dati che danno luogo ad altri dati, senza né escludere tecnicamente la possibilità di risalire ai singoli profili, né tantomeno eliminare la possibilità di errori o discriminazioni che attraverso algoritmi imperfetti o scorretti ledano il consumatore (a questo proposito C. Busch, *Implementing Personalized Law: Personalized Disclosures in Consumer Law and data Privacy Law*, in *The University of Chicago Law Review*, cit., pp. 321-324 dove si sostiene come in riferimento all'informazione «*the wave of the future might be a mix between personalized privacy defaults implemented through privacy assistants and only occasional active choices about data sharing*»).

[45] In argomento si vedano C. Colaprietro, A. Moretti, *L'intelligenza artificiale nel dettato costituzionale: opportunità, incertezze e tutela dei dati personali*, in *BioLaw Journal*, 3/2020, p. 379.

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organizzazioni internazionali[46], ma di favorire più ampi obiettivi di economia circolare e nuove strategie di produzione di cibi e di prodotti alimentari attente all'impatto climatico[47]. Un alimento sprecato coinvolge oltre a profili strettamente etici anche complessi profili ambientali: invero per stimare il suo impatto sull'ambiente è necessario avere debita considerazione del suo intero ciclo di vita attraverso indicatori specifici, come quello del *carbon footprint*, dell'*ecological footprint* e, non da ultimo, del *water footprint*[48]. Si tratta di indicatori che nel loro insieme richiamano quella che appare una delle sfide più attuali ed affascinanti per la *european consumer law*, vale a dire la protezione dei cd. *climatarian consumers*[49].

In questa stessa prospettiva di contenimento e di incentivo alla sostenibilità attraverso l'uso dell'intelligenza artificiale si collocano altre opportunità. Si pensi alle

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[46] Secondo una ricerca condotta da SIWI (*Stockholm International Water Institute*), sulle perdite e sprechi che si verificano lungo tutta la filiera ('*From Farm to Fork*') a livello globale, solo il 43% dei prodotti coltivati a scopo alimentare viene effettivamente consumato (cfr. J. Lundqvist, C. de Fraiture, D. Molden, *Saving Water: From Field to Fork – Curbing Losses and Wastage in the Food Chain*, SIWI, 2008). Le Istituzioni dell'UE e le principali Organizzazioni internazionali (FAO, UNEP, USDA, G20) hanno inserito nei documenti programmatici, come priorità strategica, la riduzione dello spreco alimentare. Nel settembre 2015 è stato adottato dall'Assemblea Generale delle Nazioni Unite, nel quadro dell'Agenda 2030 per lo Sviluppo Sostenibile, l'obiettivo di dimezzare lo spreco alimentare. L'obiettivo 12 - Consumo e produzione responsabili, al target 12.3 auspica che si possa dimezzare, entro il 2030, lo spreco alimentare globale pro-capite a livello di vendita al dettaglio e dei consumatori e ridurre le perdite di cibo durante le catene di produzione e di fornitura, comprese le perdite del post-raccolto.

[47] Tra i tentativi interessanti si può annoverare 'Giuseppe', un'intelligenza artificiale creata dalla start up cilena 'NotCo' in grado di elaborare formule alimentari nuove – il nome stesso vuole evocare la fantasia e l'estro del pittore Giuseppe Arcimboldo –, e realizzate senza l'uso di tutti quei derivati animali considerati 'impattanti' per la salute del Pianeta.

[48] I diversi obiettivi vanno tra loro connessi nel quadro di una compiuta concezione dell'economia circolare, quale è quella dell'*'end of waste*', ossia il processo attraverso il quale un rifiuto, sottoposto ad un'operazione di riciclo o di compostaggio, possa essere trasformato in materia prima utilizzabile in altro processo produttivo, così come delineato dall'art. 6 della Dir. 98/2008, come modificata dall'art. 1, par. 1, punto 6 della Dir. 851/2018.

[49] Si tratta di un tema attualissimo, che coinvolge il diritto del consumatore alla corretta informazione sulle scelte alimentari che compie, in termini di sostenibilità e preservazione delle risorse naturali. Forme di etichettatura attente agli obiettivi menzionati sono attualmente rimesse alle iniziative dei privati (https://foodinstitute.com/focus/carbon-labeling-gains-momentum-despite-challenges/) con inevitabili perplessità in relazione alla possibile strumentalizzazione commerciale dei prodotti attraverso operazioni di mero *green washing*.

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cd. *vertical farmings* coltivate attraverso tecnologia aeroponica vale a dire al sostentamento artificiale di piante attraverso la nebulizzazione di acque arricchite che investono direttamente l'apparato radicale della pianta senza l'uso della terra. Si potrebbe dire che gli obiettivi di *food sustain*ability promuovono a loro volta obiettivi di *food security*, poiché attraverso strumenti di intelligenza artificiale è attualmente possibile contribuire al miglioramento dell'agricoltura come pure alla preservazione delle attività svolte dai piccoli agricoltori, la cui alea di profitto ne scoraggia l'impegno. A questo proposito l'*agri-food tech* già svolge un lavoro essenziale; si pensi alla gestione dell'irrigazione ed agli innegabili effetti in termini non solo di prodotto finale, ma anche di uso ponderato dell'acqua quale bene comune[50].

5. Brevi riflessioni conclusive

L'uso dell'intelligenza artificiale permette di realizzare scelte di consumo sostenibile ed in linea con gli obiettivi di tutela ambientale del TFUE (in modo particolare artt. 191-193), come pure consente il perseguimento delle finalità del Green Deal europeo attraverso una rinnovata scatola degli attrezzi che il *tech food* offre al giurista[51]. Lo stesso documento della Commissione europea noto come 'Farm to Fork Strategy' (2020) sottolinea come i metodi di produzione agricola siano chiamati a ridurre l'agrochimica, i fertilizzanti, gli antibiotici e ad accrescere la sostanza organica

[50] Operazioni di Smart AgriFood applicando tecniche di intelligenza artificiale (come ad esempio sensori, droni, dispositivi di *Iot*) possono fornire una soluzione a tutti quei problemi della produzione agroalimentare che non possono essere risolti con approcci e strumenti tradizionali o che comunque richiedono standard di efficienza e produttività così come fatti propri dalla società occidentale (cfr. B. Rollin, *Agriculture, Ethic and Law*, in G. Steier-K.K. Patel (eds.), *International Food Law and Policy*, Springer, 2016, p. 35).

[51] Il tema trova diversi spunti di riflessione in F. Khajehei, C. Piatti, S. Graeff-Hönniger, *Novel Food Technologies and Their Acceptance*, in C. Piatti, S. Graeff Hönniger (eds.), *Food Tech Transitions Reconnecting Agri-Food, Technology and Society*, cit, p. 18 dove si sottolinea come «research and food techs development have been focusing on innovative food technologies to be able to adapt to the growing demand for sustainability in terms of energy and water consumption, preservation of nutritional value of food products, reduction of food waste and ensuring food safety» (p.18).

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per catturare CO2 nel suolo (carbon farming), incentivando le innovazioni tecnologiche e digitali idonee per tali fini[52].

Sebbene l'uso delle innovazioni tecnologiche e dell'intelligenza artificiale possa migliorare la *food safety* europea e più ampiamente globale, un'attenzione specifica deve tuttavia essere rivolta all'uso della biotecnologia ed all'uso dei dati. Per un verso, gli obiettivi di *food safety* devono essere contemperati con la tutela della biodiversità e della sovranità alimentare. Per altro verso, la tutela della food safety deve poter far uso su dati 'ufficiali', diversamente si rischia di vulnerare alcuni diritti cruciali del consumatore come pure i diritti e le garanzie consone ad una società sempre più multiculturale.

Invero, nell'esperienza europea emerge un'alta attenzione verso tutte le innovazioni idonee a migliore la *food safety* attraverso l'intelligenza artificiale, ma allo stesso tempo emerge una chiara consapevolezza sulla necessità di dover porre in atto tutte le misure necessarie per bilanciare la capacità d'innovazione dell'intelligenza artificiale con la protezione dei valori e dei diritti fondamentali dell'Unione Europea, affinché la logica dell'innovazione ed il fervore della competitività con gli Stati Uniti e la Cina non prenda il sopravvento sulla logica della persona e sui diritti ad essa riconosciuti nel contesto europeo[53].

Nel quadro giuridico sovranazionale il problema cruciale è quello di trovare un equilibrio condiviso tra l'esigenza di poter fare affidamento su nuove regole ad hoc e la possibilità di risolvere le complicazioni che emergono in sede interpretativa con gli strumenti giuridici attualmente a disposizione. Si tratta di una tensione cruciale che esula dai confini nazionali proprio in ragione dei valori coinvolti; al di là di un uso dei *big data* come forza innata degli strumenti di intelligenza artificiale e delle

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[52] Cfr. A. Frascarelli, *La rivoluzione verde che può favorire l'agricoltura italiana*, in *L'Informatore agrario*, 21, 2020, p. 5.

[53] In relazione ai poteri di intervento della cd. '*algorithm legibility*' si vedano G. Malgieri, G. Comandè, *Why a Right to Legibility of Automated Decision-Making Exists in the General Data Protection Regulation*, in *International Data Privacy Law*, 7, 2017, pp. 243 e ss. Per un'analisi sulle disposizioni introdotte da parte di alcuni Stati membri a favore dei diritti delle persone coinvolte da processi decisionali automatizzati con riferimento ai limiti dell'art. 22 del Reg. UE 679/2016 si rinvia a G. Malgieri, *Automated Decision-Making in the EU Member States: The Right to Explanation and Other "Suitable Safeguards" in the National Legislations*, in *Computer Law & Security Review*, 35, 2019, open access.

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problematiche del consenso nelle relazioni B2C o B2B, la preservazione dell'ambiente e la garanzia della *food safety*, quali riflessioni basilari di questo lavoro, sono per antonomasia problemi globali[54]. Di essi il *comparative lawyer*, proprio per sua vocazione al dialogo interdisciplinare, è chiamato a farsi promotore nella piena consapevolezza che il formante legislativo incede con passo lento rispetto allo sviluppo tecnologico[55].

[54] Cfr. F. Albisinni, *Diritto agro-alimentare e metodo comparativo: oggetto, strumenti e prospettive*, in L. Scaffardi-Z. Zeno-Zencovich (eds.), *Il cibo e il diritto. Una prospettiva comparata*, cit, p. 191.

[55] Si parla al riguardo di '*pacing problem*'; cfr. G. Marchant, *Addressing the Pacing Problem*, in G.E. Marchant-B.R. Allenby-J.R. Herkert (eds.), *The Growing Gap between Emerging Technologies and Legal-Ethical Oversight*, Springer, 2011, p. 200.

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The integration of informal business law in the OHADA framework. Methodological reflections

Salvatore Mancuso (*)

Abstract

OHADA represents today a successful example of legal integration that offers a modern and reliable legal environment regarding business law in those countries that have joined it. However, such a modern integrated system of business law appears to be unsuited to the informal business sector that still represents a vital segment of the economy in most of the African countries. The paper discusses the attempts that have been made to integrate the informal business sector in the OHADA framework, trying to understand the reasons why they have been substantially unsuccessful and suggests a possible way forward to make such integration possible.

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Keywords
African law, informal sector, business law, OHADA, legal pluralism

1. A taxonomy of the informal sector

The informal sector is a fluid area that usually escapes from a stable categorization[1]. To a jurist who is always seeking for a taxonomical approach, the exercise is complicated even further, since the informal sector tends to elude formalization and to operate in a quasi-legal or, even more, extra-legal environment. A definition that captures the main characteristics of the phenomenon identifies the informal sector in the "*[…] semi-organised and unregulated activities largely undertaken by self-employed persons in the open markets, in market stalls, in undeveloped plots of street pavements within urban centres. They may or may not have licenses from local authorities for carrying out such activities*"[2].

The result of the above definition is that the informal sector includes activities usually, but not exclusively, conducted in open or temporary structures, in urban and rural areas. The size of the business is extremely small, with extremely low capital involved, without official bookkeeping, and without or with an extremely low number of employees, then such is likely to be informal or, at most, of a small scale[3].

[1] There are many definitions of the "informal sector". In its 1972 report "Employment, incomes and equality: A strategy for increasing productive employment in Kenya" at 6 the ILO defined "informal activities" as "the way of doing things, characterised by (a) ease of entry; (b) reliance on indigenous resources; (c) family ownership of enterprises; (d) small scale of operation; (e) labour-intensive and adapted technology; (f) skills acquired outside the formal school system; and (g) unregulated and competitive markets. Informal-sector activities are largely ignored, rarely supported, often regulated and sometimes actively discouraged by the government".

[2] Central Bureau of Statistics of Kenya, cited in K. Kibwana, 'Critical aspects regarding the legal regulation of the informal sector', (1989) Vol. 5, No. 2 Lesotho L. J., 357.

3 Ibid., 361.

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Therefore, the informal sector normally embraces the part of the economy not documented for purposes of the official count of GDP[4].

Although the activities performed in the informal sector are not necessarily illegal, illegal businesses and tax evasion are phenomena that are also part of the informal sector[5]. This explains why literature has recognized that the informal sector suffers from a negative public image, even if it has many positive characteristics and has a vital role in contributing to the economic growth of the continent. However, a distinction has been developed between the informal and the underground economy. The former is the one conducted legally but without the formalities requested by the official law, and the latter covers the market production of legal and illegal goods and services that are sold or bought illegally and includes the shadow economy, where legal goods and services are produced and traded under illegal conditions, and black markets[6]. Having considered the above, in this paper, then, attention will be paid to the legal businesses in the informal sector, made normally by nano-entrepreneurs or own-account workers[7].

The variable conditions for conducting the business activity, the extremely small dimensions of the activities whose consequence is the small number of workers employed in each activity when not conducted by a sole nano-entrepreneur, and the low propensity to the formalization of the informal activities have been considered the main characteristics of the informal sector[8]. However, informal sector activities require little capital to create jobs, work essentially on family savings, are a fundamental source of new jobs for the increasing labour force in Africa, and are the

4 F. Schneider, 'Size and Measurement of the Informal Economy in 110 Countries around the World', Discussion Paper Australian National Tax Centre, ANU, Canberra, Australia.

5 F. Schneider, D. H. Este, 'Shadow Economies: Size, Causes, and Consequences' (2000) 38 J. Econ. Lit.,79.

6 P. Lemieux, 'L'économie souterraine: causes, importance, options'; [2007] Montréal, Les Cahiers de Recherche de l'Institut Économique de Montréal.

7 C. M. Dickerson, 'OHADA on the Ground: Harmonizing Business Laws in Three Dimensions', (2010) 25 Tulane European & Civil L. Forum, 10, at 112 and ff.

8 S. Kwemo, *L'OHADA et le secteur informel*, (Bruxelles, Larcier, 2012).

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main business activities in town markets and small urban centres[9]. In general, the dynamism of the informal sector in creating employment and value addition is particularly strong, representing about 80 per cent of the total labour force[10], and contributing about 55 per cent of sub-Saharan Africa's GDP[11].

However, assuming the existence of an identifiable informal sector means inevitably simplifying reality. The boundaries of this sector with the formal sector are extremely flexible and even porous. Many actors of the informal sector operate also in the formal sector at the same time, often even at different levels of the same chain. Such coexistence of the formal and informal sectors at the same time can be found – for example – in the case of the West African *nana benz*, who are wholesalers and informal retailers at the same time[12]. This happens since they purchase goods from the general suppliers using standard commercial contracts, goods that are after resold to the nano-entrepreneurs in the street markets through informal contractual instruments. Since the demarcation so vague, it is often very difficult to identify which

9 Sessional Paper No. 1 of 1986, Economic Management for Renewed Growth, Nairobi, Government Printer, 54.

10 The International Labour Organization reported that, depending on the country, in sub-Saharan Africa the informal sector employed between 39% and 71% of all non-agricultural workers. International Labour Organisation (ILO), "Women and Men in the Informal Economy: a Statistical Picture", 2nd ed. (2013), available at <http://www.ilo.org/wcmsp5/groups/public/---dgreports/---stat/documents/publication/wcms_234413.pdf>.

11 African Development Bank, "Recognizing Africa's Informal Sector" (27 March 2013), available at http://www.afdb.org/en/blogs/afdb-championing-inclusive-growth-across-africa/post/recognizing-africas-informal-sector-11645/ (21 October 2016). Data about the size and the contribution of the informal economy to sub-Saharan Africa GDP are conflicting: according to a report released by the IMF, "the share of informal economic activity in Sub-Saharan Africa remains among the largest in the world, although this share has been very gradually declining, as seems to be the case globally. The SSA unweighted average share of informality reached almost 38 percent of GDP over 2010-14", see L. Medina, A. Jonelis, and M. Cangul, The Informal Economy in Sub-Saharan Africa: Size and Determinants, IMF Working Paper WP/17/156, July 2017.

12 This is an appellation used to describe businesswomen who wear typical African clothes and are likely to own Mercedes Benz cars.

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activities are in this or that sector. Thus, the reference to the informal sector as some kind of monolithic reality has to be done merely to facilitate discussion[13].

2. The informal sector and the law in Africa…

The informal sector tends to escape the rigidity of legal regulation, and the informal entrepreneurs very often do not look for registration according to the relevant laws as they consider that the benefits of formalizing are not large enough to compensate for the costs of formalizing: the consequence is that informal business are not productive enough to survive as formal enterprises.[14]

Legal constraints are only one of the factors affecting the decision of an entrepreneur to opt for the informal sector. A study conducted in Côte d'Ivoire reveals that the main obstacles to the formalization of informal businesses are: the administrative formalities of starting a business (21.92%), the narrowness of the market (17.03%), the ignorance of the procedures (16.48%), high taxes and social security contributions (16.21%) and high registration costs (11.05%)[15].

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13 C. M. Dickerson, 'OHADA's Proposed Uniform Act on Contract Law. Formal Law for the Informal Sector', (2011),13 Eur. J.L. Reform 462.

14 R. La Porta, A. Shleifer, 'The Unofficial Economy and Economic Development', Brookings Papers on Economic Activity, (2008), 275. According to van Elk and de Kok, the following costs of becoming and remaining formal are usually distinguished: entry costs (the time required to go through all of the required procedures to get registered and the licence or registration fees that have to be paid), formal operating costs (the costs associated with operating in the formal economy: taxes, fees and social contributions), and compliance costs (costs of complying with labour regulations, the time required to obtain property registration and apply for formal loans, inefficient contract enforcement mechanism, etc.). See K. van Elk, J. de Kok, 'Enterprise formalization: Fact or fiction?', (2014) ILO-GIZ, available at https://www.ilo.org/wcmsp5/groups/public/---ed_emp/---emp_ent/ifp_seed/documents/publication/wcms_245359.pdf,

15 Cellule d'Analyse de Politiques Économiques du CIRES (CAPEC), Encadrement du secteur informel: source de croissance et de compétitivité de notre économie, (2018) Abidjan, available at http://agencecipme.ci/wp-content/uploads/2018/04/Rapport_CCESP_CAPEC-_14FEVRIER-2018.pdf.

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The theme is therefore whether this Western (French, in the case of OHADA) approach to business law, based on legal positivism and high technicalities, can be effectively transplanted in Africa and it is suitable to embrace its business environment in its entirety.

The African jurists who examine the law through the Western lens that they learnt at university will immediately answer affirmatively. But such an answer does not take into consideration the fact that such law is applicable to a small elite capable of understanding it, and willing and able to apply it. Western commercial law has evolved using legal concepts and technicalities that were developed by Western legal culture over time, and only a jurist trained using Western concepts can understand them, since these are not contemplated in African traditional legal culture. This also seems to be the limitation of the OHADA system of harmonized business law.

Moreover, just as there is official law and unofficial law in Africa[16], there is also – as noted above – an area of official commerce and a wider area of informal commerce, both equally important to the State economy. These two types of commerce co-exist in most African countries, and informal commerce does not comply with official legal rules, which are too complex and lacking the flexibility necessary to run an informal

[16] Reference is made here to the law the issued by the official legislative authorities and to law emanating from alternative sources and generating further normative orders that are often competing with the official state law. Scholars today distinguish between official and living (or unofficial) customary law (on this distinction see, for example, T. W. Bennett, 'Official vs 'Living' Customary Law: Dilemmas of Description and Recognition', in A. Claassens and B. Cousins (eds.), *Land, Power & Custom: Controversies Generated by South Africa's Communal Land Rights Act*, (2008) Cape Town, JUTA, 138; C. N. Himonga, C. Bosch, 'The Application of African Customary Law Under the Constitution of South Africa: Problems Solved or Just Beginning', (2000) 117 South African Law Journal, 306, where official customary law would be the one endorsed or produced by the State through codification or restatement tools, or through precedents or jurisprudential decisions that seek to identify and apply it, while living customary law would be made up of the system of rules that people apply on a daily basis, and which does not need any official state intervention to be produced, modified and applied. Apart from the strong criticism to the definition of such kind of law as "customary", such distinction lends itself to further criticism, as when it has become "official", this law could not be still defined as "customary", since it lost all the main characteristics of such form of law (on the criticism to this dichotomy see also A. C. Diala, 'The Concept of Living Customary Law: A Critique', (2017) 49, No. 2, Journal of Legal Pluralism and Unofficial Law, 143.

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business; therefore, the informal sector has developed its own set of rules that exist outside of the official legal systems of each nation.

If the legal order in the area of business law is characterized by written rules imposed by the state, then the legal principles among informal tradesmen are characterised by the persistence of orality which remains their main means of expression[17]. Contracts of purchase or sale, transport or delivery, performance of services or mandates, in short, commercial contracts, are concluded verbally. Despite these contracts being unwritten, the parties involved easily remember all the obligations resulting from their verbal engagements, even if certain arrangements are concluded in the presence of witnesses or receipts or other simple written instruments are used to ensure the safety of the transactions[18].

Resorting to legal orality and not reducing contracts to writing favours simplicity and avoids heavy formalism: the main obligations arising from the verbal contract are simply formulated with all the parties, in easily comprehensible terms and therefore can be easily remembered by them. Ultimately, the entrepreneurs in the informal sector do not act or move in a zone of non-law or illegality. They establish business transactions according to their beliefs and carry them out because people's words are respected, so very seldom a contract obligation is not respected as trust is one of the main elements that determines the entering into a contractual agreement. Business relations between the parties are based more on mutual trust and politeness than on formal instruments derived from the official law[19]. Recourse to writing is therefore not excluded in principle from commercial relations among them, but it may be considered unnecessary.

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[17] O. Ballal, *Les usages et le droit OHADA*, (Aix-Marseille, PUAM, 2014, 57).

[18] S. Kwemo, 'L'OHADA' cit.; S. Bissaloue, 'L'informel et le droit OHADA' in A. Noel Gbaguidi, J. Djogbenou, E. Montcho Agbassa (eds.), *Les horizons du droit OHADA: Mélanges en l'honneur du Professeur Michel Filiga Sawadogo*, (2018) 487; O. Ballal, 'Les usages' cit.

[19] C. M. Dickerson, 'Bringing Formal Business Laws to Cameroon's Informal Sector: Lessons and Cautions from the Tax Law Example', (2014) 13 n. 2, Washington Univ. Global Studies L. Rev., 267, at 283.

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Most informal entrepreneurs do not meet the requisites required by the official law that would give them access to the official credit system for setting up and running their business[20]. The alternative for them is therefore to resort to different instruments of financing like the *tontine*[21], which has become one of the pillars of today's African informal economy (especially in West Africa) despite not being directly related to commercial activities and not constituting a commercial act (*acte de commerce*) according to official business law. Practice developed countless different variations from the original concept of *tontine* in Africa, but they all present some essential elements, namely a number of participants, the periodic deadlines, the rotating contributions and withdrawals. They operate in a standard way of paying fixed sums at regular intervals, and all members in turn withdraw from the payments. The pressure of the other members, whose ties may be multiple (inhabitants of the same neighbourhood, sex or age, family relations or belonging to the same ethnic group), ensures the participation of each member. Each group also has a leader or a recognized organizer of the *tontine*. As far as participation in terms of membership is concerned, there is no "ideal" size: the size varies according to the task and character of its members or group leaders, but also by gender, or also age. The group of people participating to the *tontines* do not fall under the application of the official law, as they are not based on any contract: these associations have no legal status, and in case of

[20] There is a wide literature on this subject. Some examples are: M. Lindvert, 'Financial Barriers and How to Overcome Them: The Case of Women Entrepreneurs in Tanzania', in A. Akinyoade, T. Dietz and Chibuike Uche (eds.), *Entrepreneurship in Africa*, (2017) Brill, 344; F. Gire , K. Mellet, A. Saïdali, 'Financial practices of Dakar's informal sector entrepreneurs and mobile money', available at https://hellofuture.orange.com/en/financial-practices-of-dakars-informal-sector-entrepreneurs-and-mobile-money; B. S. Morewagae, M. Seemule, H. Rempel, 'Access to Credit for Non-Formal Micro-Enterprises in Botswana', (1995) 31, n.3 ,Journal of Development Studies, 48; C. Grey-Johnson, 'The African Informal Sector at the Crossroads: Emerging Policy Options', (1992) 17 n.1 Africa Development/Afrique et Développement, 65. More in general, on the financing of small businesses, with a case study on Vietnam, see Bach Nguyen, Nguyen Puch Canh, 'Formal and informal financing decisions of small businesses',(2021) 57 Small Business Economics", 154.

[21] The word tontine identifies a phenomenon that takes place in mainly West Africa and in the French-speaking African countries in particular, where lending money is based on exchange and solidarity.

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conflict, everything is settled amicably among the members, otherwise reference is made to rules of informal law[22].

Sometimes the writing or legal orality is not exclusive to one or other of the two business sectors. It is not rare to resort to legal orality in the commercial relations between a formal and an informal businessman. The case of the West African *nana benz* is a clear example in this respect. The *nana benz* are businesswomen officially registered with the trade registrar, who respect the legal obligations imposed by membership thereof, enter into regular contracts with their suppliers, but prefer not to enter into formal contracts with their informal retailers for the sale of the goods they supply them. However, when the informal retailer is a beginner in the area of purchase and resale, a very concise written agreement might be concluded between the parties. Digital fingerprints are affixed to the bottom of the document, which mentions the expiry date, the identity of the parties, and the sum that the informal retailer must repay to the other party after the resale of the goods.

In case of late payments or instalments, interests are normally not charged as they are not conceived in the African legal culture[23]. Legally binding situations derived from time[24], such as forfeiture, prescription or interest rate are not recognized. The reason is that the traditional concept of time is different in Africa compared to the

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[22] A. Ependa, 'Typologie et aspects organisationnels des tontines dans le contexte d'une économie sociale informelle à Kinshasa', (2002), available at http://constellation.uqac.ca/2013/1/030120696T1.pdf. Tontines have been extensively studied by French authors like M. Lelart, 'L'épargne informelle en Afrique. Les tontines béninoises', (1989), 30 n. 118 Tiers-Monde, 271; A. Ependa, 'Typologie' cit.; C. Mayoukou, 'Le système des tontines en Afrique. Un système bancaire informel', (L'Harmattan 1994); A. Kane, 'Tontines, casses de solidarité et banquiers ambulants', (L'Harmattan 2010). On the different forms of rotating credit associations in Africa see S. Mancuso, 'Tontines and other Forms of Rotating Credit Associations in Africa', in P. Hellwege (ed.), *Comparative Studies in the History of Insurance Law*, (Duncker & Humblot 2018).

[23] S. Mancuso, 'OHADA law and its target population: is there room for African traditional law within the harmonisation of contract laws in Africa?', in C. Rautenbach (ed.), *In the Shade of an African Baobab: Essays in Honor of Thomas Bennett*, (JUTA 2018).

[24] M. Alliot, 'Les résistances traditionnelles au droit moderne dans les états d'Afrique francophone et à Madagascar', in C. Kuyu (ed.), *Le droit et le service public au miroir de l'anthropologie*, (Karthala 2003).

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West[25]. In Africa, time has traditionally been linked to other factors such as market cycles or crops[26]. Thus, the payment of the price of any item is considered to be verified "at the same time" of the fulfilment of the other contractual obligation, even it has been effectively made after several days or months[27].

In general, the contractual obligation does not involve exclusively the party that contracted it, but all members of its family or community that is – in its entirety – affected by the contract entered into by one of its members. Within the communities, contractual relations are based on mutual trust, while testimony or written instruments (if the parties are literate) will support the entering into a contract when the parties belong to different communities[28].

Enforcement of contractual obligations is not brought to the formal court system, but it is rather done by turning to the informal courts in the markets or reporting the event to the police. The latter does not formally enforce official law but uses its authority while acting as public order officer, judge, and mediator at the same time. The result is an *ad hoc* enforcement of the basic rule to repay obligations without following any rules of procedure, that is considered highly irregular from a formal-law perspective[29].

While the official business law is based on the formalism derived from the Western pattern, the simplicity of the above-mentioned alternative instruments clearly shows the profound gap existing between formal and informal law. Such gap is a sign of the more general difficulty to apply official law to the informal business due to the requirements, formalisms and technicalities that official law got from the Western approach to law. The result is the creation of a parallel set of rules outside of the

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[25] A. A. Da Silva, *Usos e costumes jurídicos dos Mandingas*, (1969).

[26] M. Aime, *La casa di nessuno. I mercati in Africa occidentale*, (Bollati Boringhieri 2002).

[27] J. Vanderlinden, *Coutumier, manuel et jurisprudence du droit zande*, (Éditions de l'Institut de sociologie, Université Libre de Bruxelles; 1969), A. A. Da Silva, *Usos e costumes* cit.

[28] O. Ballal, *Les usages* cit., at 46 and ff.

[29] C. M. Dickerson, *Bringing* cit., at 284.

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official system more rooted int the African legal culture, as the following example shows.

In Somalia, where a civil war has raged since 1991 causing the absence of a fully functional central government up (at least) to 2012, three phone companies engaged in fierce competition for both mobile and landline customers as well as for internet services. Since there is no need to obtain a licence, there is no state-run monopoly which prevents the emergence of new competitors, and the prices are the lowest in Africa since taxes are not collected. But what is more significant is the fact that, despite the lack for a long time of production of official law and its application by a functioning court system, bills are paid, and contracts are enforced, by relying on Somalia's traditional clan system[30].

3. …with particular reference to OHADA

The formal business laws do technically and officially apply over transactions within the informal sector.

In the case of OHADA, modern business laws have been enacted by giving an African flavour to the French rules on the sectors that have been harmonized. This is because those who prepared the draft Uniform Acts at the beginning were French jurists who used the model with which they were familiar, and which seemed more appropriate for the countries where the new legislation was to be introduced. Moreover, this activity has been facilitated by the Western scholars' traditional approach, based on the assumption that commercial law is one of the areas where state laws have a monopoly, since the area of commercial law is not usually covered by African traditional law.

The OHADA Treaty has created a series of institutions, namely a Council of Heads of State and of Government, a Council of Ministers (having legislative competence), a Permanent Secretariat (having executive competence), a supranational Common

[30] See more in S. Mancuso, 'Pluralismo giuridico in Somalia. Trascorsi storici e sviluppi recenti', (2014) 9 Iura Gentium 140.

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Court of Justice and Arbitration (CCJA), and a centre for training legal professionals on the OHADA system (ERSUMA)[31]. Furthermore, every member country has an OHADA national commission whose task is to comment and propose amendments – mainly from a national perspective – to the draft uniform acts. According to the Treaty, ten uniform acts that already provide substantial coverage of business transactions and relationships have been already adopted[32]. The OHADA legislative acts are named "Uniform Acts" since they become part of the internal domestic law of each of the OHADA member states automatically and without modification after having been adopted pursuant to the procedures set out in the OHADA Treaty and published in the OHADA Official Journal. Furthermore, these Uniform Acts replace any existing or future laws on the same subject in all member States[33]. The uniform acts are enforced through the national courts, up to the second instance, since the national supreme courts do not have jurisdiction on final appeals where OHADA uniform acts apply: when a case where OHADA laws shall apply shall be decided by the court of final instance, it is appealed to the CCJA, located in Abidjan,

[31] Art. 27-41 OHADA Treaty.

[32] Acte Uniforme relatif au Droit des Sociétés Commerciales et du Groupement d'Intérêt Economique, 17 April 1997, 2 J.O. OHADA 1, revision adopted 30 January 2014, J.O. OHADA 1 (Special Edition, 4 February 2014); Acte Uniforme portant sur le Droit Commercial Général, 17 April 1997, 1 J.O. OHADA 1, revision adopted 15 December 2010, 23 J.O. OHADA 1 [hereinafter "General Commercial Law"]; Acte Uniforme portant Organisation des Sûretés, 17 April 1997, 3 J.O. OHADA 1, revision adopted 15 December 2010, 22 J.O. OHADA 1 [hereinafter "Securities Law"]; Acte Uniforme portant Organisation des Procédures Simplifées de Recouvrement et des Voies d'Exécution, 10 April 1998, 6 J.O. OHADA 1; Acte Uniforme portant Organisation des Procédures Collectives d'Apurement du Passif, 10 April 1998, 7 J.O. OHADA 1, revision adopted 10 September 2015, J.O. OHADA n. spec. 25 September 2015 1; Acte Uniforme relatif au Droit de l'Arbitrage, 11 March 1999, 8 J.O. OHADA 1, revision adopted 23 November 2017, J.O. OHADA n. spec. 15 December 2017 1; Acte Uniforme portant Organisation et Harmonisation des Compatibilités des Entreprises, 22 February 2000, 10 J.O. OHADA 1, revision adopted 26 January 2017, J.O. OHADA n. spec. 15 February 2017 1; Acte Uniforme relatif aux Contrats de Transport de Marchandises par Route, 22 March 2003, 13 J.O. OHADA 3; Acte Uniforme relatif au Droit des Sociétés Coopératives, 15 December 2010, 23 J.O. OHADA 1; Acte Uniforme relatif à la Médiation, 23 Novembre 2017, J.O. OHADA n. spec. 15 December 2017. All uniform acts can be accessed from the OHADA website www.ohada.org.

[33] Art. 10 OHADA Treaty.

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Coôte d'Ivoire[34]. To secure a uniform interpretation and application of the OHADA uniform acts in all member countries, the CCJA decides both on the interpretation and application of the OHADA uniform acts and on the merits of the case, and therefore the case is never sent back to the domestic courts for further decision.

When OHADA uniform acts are not applicable, national legislation will be applied depending on the place where the transaction took place and according to the rules of private international law if applicable.

The techniques through which OHADA uniform acts are formulated and implemented, as well the long-lasting process necessary for their updates and changes show their high level of "rigidity", and, consequently, their dissonance with the daily realities of those who operate in the informal business sector. As it has been observed, it appears "that the regime pays more attention to regulating transactions involving big businesses and multinational corporations than it does to regulating transactions involving smaller businesses or even the informal economy, which is the driving force of African economies in the region"[35].

Several examples can be made in this respect[36].

The Uniform Act on General Commercial Law regulates the commercial sale and provides a series of guarantees that the seller shall provide to the buyer about the quality of the goods[37]. Therefore, vendors in the informal markets have a series of rights against suppliers pursuant to the above-mentioned rules on warranties, as well as obligations to customers as to the quality of goods they sell under the same

[34] Art. 13-16 OHADA Treaty.

[35] C. M. Fombad, 'Some reflections on the prospects for the harmonization of international business laws in Africa: OHADA and beyond', available at https://repository.up.ac.za/handle/2263/31659, at 15 and ff., and published in (2013) 59 Africa Today n. 3, 51. See also Olga Ballal, Les usages cit., at 44.

[36] For a wider discourse on this issue see S. Kwemo, *L'OHADA* cit.

[37] These guarantees refer mainly to the conformity of the goods to the contractual agreement and from being free from third parties' rights. They are indicated in Section 3, Chapter 1, Title III of the Uniform Act on General Commercial Law, revised version (2010), Articles 255-261.

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uniform act if the customer is also a business actor, or under the rules concerning consumer protection if the buyer is a normal consumer. The practice tells us that the informal-sector entrepreneurs did not appear, both as buyers and as sellers, to make use of the rights and obligations provided by the formal law about quality; and, similarly, consumers do the same. As it has been observed, "there could be market reasons, such as the preference for lower prices, that would induce buyers to refuse the benefit of warranties. Nevertheless, buyers' consistent neglect to demand a warranty could provide further indication that they did not perceive the laws as reliable"[38].

In its original version, the Uniform Act on Company Law required the presence of a notary public in order to comply with most of the formalities required by the Act, giving exclusive powers to this professional. In most cases notaries public are present only in the capital cities and in the big towns, and it is inconceivable that a person from a village or the rural area would travel to the town simply to sign something before a notary public because a written law requires it, and when that person probably does not even know about the law. This because there are logistical challenges in Africa, and all travelling involves considerable time and money[39].

The business environment plays an important role in the development of enterprises and in particular informal production units. In the study conducted in Côte d'Ivoire, access to finance is considered a major problem for 35.58% of informal businesses[40]. Indeed, due to their extreme small size, informal businesses do not have possibility to access the formal channels to get credit when they need it, since credit institutions are unlikely to have relations with unregistered businesses;

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[38] C. M. Dickerson, *Bringing* cit., at 280.

[39] The OHADA legislator tried to find a solution to this problem by providing, in Article 10 of the new version of the Uniform Act on Company Law adopted in 2014, that the articles of association of the company are drawn up by notarial deed or by any deed offering guarantees of authenticity in the State of the registered office of the company filed with acknowledgment of writings and signatures by all the parties having the same rank of the minutes of a notary.

[40] Cellule d'Analyse de Politiques Économiques du CIRES (CAPEC), Encadrement cit.

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therefore, most informal sector businesses rely on family savings, or other sources of financing. The formal legal sector is not helping in this respect.

The OHADA Uniform Act on Securities, even in its revised version, indicates the mortgage as the only available security over immovable, but a survey on land in 16 out of the 17 OHADA member countries showed that less than 5% of the total land is registered[41], rendering therefore mortgage substantially impracticable, and pushing consequently those in need of money to find alternative sources. And this without mentioning the issues determined by the difficulty to register the community ownership of land according to a Western based land registration system where only the individual (natural or legal person) can be recognized (and registered) as the owner[42]. Situations like this make access to credit extremely difficult (if not impossible), can cause a high mortality rate in the informal businesses, and therefore informal entrepreneurs have to resort necessarily to the informal finance to get access to alternative sources of credit.

A short overview about the informal finance is worthwhile at this point[43].

The informal finance can be defined as the set of those original mechanisms that allow the circulation of money against a temporary accumulation of credits and

[41] P. Dima Ehongo, 'L'intégration juridique du droit des affaires en Afrique: les pièges d'un droit uniforme et hégémonique dans le droit de l'OHADA', in Étienne Le Roy (ed.) *Juridicités: témoignages réunis à l'occasion du quarantième anniversaire du LAJP* (Karthala, 137, 2006). This survey does not include Democratic Republic of Congo that was not yet a member State at that time: it is very likely that if DRC is included in the survey, the percentage indicated in the tex twill be much lower.

[42] In this respect is worth mentioning the step forward made by the Loi n 21- 2018 du 13 juin 2018 fixant les regles d'occupation et d'acquisition des terres et terrains adopted in the Republic of Congo, where in its Title II (Articles 7-16) the recognition of the traditional land ownership as undivided land ownership is regulated.

[43] Literature on the informal financial sector is extremely vast and includes studies ranging from legal to economic and sociological studies. A few authors will be cited in the following footnotes in order to provide a short overview of the subject.

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debts[44]. Therefore, the informal finance includes all those unofficial mechanisms that enable temporary circulation of credits and debts[45].

The notion of informal finance makes then reference to the informal ways of financing, including those of borrowing, loan or building up of savings, which take place out of the official circuits[46]. It represents an operational approach to the phenomenon, while the notion of informal financial sector as including all the unofficial institutions granting loans to those left out by the formal financial sector, represents a more institutional approach to the same phenomenon[47]. Informal finance becomes therefore a broad concept that encompasses that wide range of financial activities and services that take place beyond the scope of a country's formalized financial institutions and are not subject to the financial sector regulations. Informal finance is common in both urban and rural contexts and normally relies on personal relationships and socioeconomic proximity. In contrast to formal finance, most informal providers focus on one service rather than offering a bundle of services.

The existence and role played by informal financial systems, especially in developing economies, is generally recognized. Informal financial institutions are considered those playing a complementary role to the formal financial system by servicing the lower end of the market. With informal financial institutions reference is made to loans from moneylenders, landlords, and families who base the financial transaction on business or personal relationships, as well as loans from institutions such as credit cooperatives, savings and credit associations that provide financial intermediation between savers and borrowers, but do not rely on the state to enforce contractual legal obligations. They consist of small, unsecured, short-term loans

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[44] M. Lelart, *Les circuits parallèles de financement: l'état de la question*, G. Henault, R. M'Rabet, 'Communication avec Actes aux Journées Scientifiques du Réseau Entrepreneuriat de l'UREF', (1990), Financement de l'entrepreneuriat et mobilisation de l'épargne 45.

[45] C. Mayoukou, 'Le système des tontines en Afrique. Un système bancaire informel', (1994) L'Harmattan, 21.

[46] M. El Abdaimi, *La finance informelle au Maroc*, (UREF/AUPELF 1991).

[47] C. Mayoukou, *Le système* cit., 22 and ff.

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restricted to rural areas, agricultural contracts, households, individuals, or small entrepreneurial ventures; they rely on relationships and reputation and can more efficiently monitor and enforce repayment than commercial banks and other formal financial institutions[48].

The informal financial system had a remarkable development in Africa. This is caused by the concurrence of different factors, namely the rigidity of the formal banking system, its inability to adapt itself to the population's needs. The official financial system is unable to make suitable financing channels adapted to the African reality available to the informal sector and – more in general – to most of the people. Actors in the informal sector rarely have collateral acceptable to banks: their creditworthiness resides in their human capital, which is difficult for formal intermediaries to consider. Often the cost to formal institutions of opening branches in villages and small towns is not justified by the business that can be generated. The informal financial system is in these cases the only accessible option, as it plays a supplementary role to that of the formal financial system.

Informal financial arrangements reduce transaction costs and risk using instruments not available to formal institutions. Those running informal financial activities can operate out of their own homes or on the street, maintain only the simplest accounts, and mix finance with other business. Freedom from control by the official financial authorities allows informal finance greater flexibility. However, such freedom also does not allow the use of many of the legal remedies available to formal intermediaries. Differently from formal legal mechanisms, informal finance relies on the knowledge of one another and on local sanctions to reduce the risk of lending. Social standing, personal reputation and the ability to obtain future financial services are often at stake in the market for informal financial services, and these sanctions showed to be effective.

All the above are the reasons why many times African savings do not adopt the forms normally used in the Western world, but rather follow mainly informal

[48] M. Ayyagari, A. Demirguc-Kunt, V. Maksimovic, 'Formal versus Informal Finance: Evidence from China', (2010) 23 (8), Rev. Financ. Stud. 3048-3097, 3048.

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channels. In this respect, *tontines* can perhaps be considered as the most representative example, definitely the most known and researched[49].

Going back to the OHADA, the discussion made above on the functioning mechanisms of the informal sector show how OHADA, the formal law, inevitably loses its centrality in the legal scenario. The existence of this gap between the official and the unofficial law has now been acknowledged, and it is significant that it is the official law that tends to be adapted to the informal reality.

The OHADA legislator introduced in the new version of the Uniform Act on General Commercial Law the "*entreprenant*", which should cope with the need to simplify the formalities required for micro and small enterprises that they cannot afford to register in the *Registre du Commerce et du Crédit Mobilier* (RCCM), particularly in rural and semi-rural areas, and through this process of "formalization", facilitate their access to formal credit and social benefits: in a nutshell, it should facilitate the official law to approach informal commerce, and in particular the entrepreneurs of the informal sector to fall within the borders of the application of the law[50]. To facilitate this process, this innovation of the OHADA legislator provides a reduced legal and accounting regime for this new legal subject. Therefore, the status of the

[49] The informality that governs the practice of tontines could clearly lead to mismanagement of the system if it is not properly run. In this respect, the rules of the OHADA Uniform Act on Cooperatives – maybe with the necessary adaptations – could be of help and represent a further meeting point between formal and informal rules.

[50] See art 30 of the revised OHADA Uniform Act on General Commercial Law. On the entreprenant see D. B. Ongono Bikoe, *L'entreprenant en droit OHADA*, (Université Panthéon-Sorbonne – Paris I, 2020, available at https://tel.archives-ouvertes.fr/tel-02943078/document); Sylvain Sorel Kuate Tameghe, entry 'Entreprenant', in P.-G. Pougoué (dir.), *Encyclopédie du droit OHADA*, (2011); J. Issa-Sayegh, 'L'entreprenant, un nouvel acteur économique en droit OHADA: ambiguïtés et ambivalence', (2012) 5 nº 878, Penant,; P.-G. Pougoué, 'L'entreprenant OHADA', (2013); S. Mancuso, 'Analyse historique et comparée de la figure de l'entreprenant en droit OHADA', in J. Diffo Tchunkam (eds.), *L'OHADA au service de l'économie et de l'entreprise*, (2014), 178; D. Tricot, 'Statut du commerçant et de l'entreprenant', (2011), n. 201, Revue Droit et Patrimoine, 67; A. Foko, 'La consécration d'un nouveau statut professionnel dans l'espace OHADA: le cas de l'entreprenant',(2010) Cahiers juridiques et politiques – Revue de la faculté des sciences juridiques et politiques, Université de Ngaoundéré, 55; M. Gonomy, 'Le statut de l'entreprenant dans l'AUDCG révisé : entre le passé et l'avenir',(2014), n.4, Revue de l'ERSUMA – Droit des Affaires, 204.

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entreprenant has been introduced with the aim of allowing entrepreneurs in the informal sector to emerge from their state of legal marginality and develop their activities in a legally and socially regulated environment, with simple and effective tax measures. Migration from the informal to the formal sector should be gradual and accompanied by measures at national level[51].

But the introduction of the *entreprenant* presents problems of systematization, as well as of interpretation, of this variation to the ordinary status of the entrepreneur. The attempt to provide a solution to a problem that is mainly African, together with the absence of the same institute or of a similar experience in terms of objectives in French commercial law and the peculiarities of how informal trade is practised in Africa, has produced a discipline that presents many obscurities[52]. Moreover, only a few member countries adopted the national operational measures to enforce the OHADA principles.

The revised version of the Uniform Act on Bankruptcy Law, in line with the introduction of the *entreprenant*, has subsequently extended the rules concerning bankruptcy to the small enterprises by providing specific regulations in this respect[53].

The revised version of the Uniform Act on Company Law has reduced the number of cases where the intervention of a notary public is requested for the validity of acts concerning companies. It has also revised the regulation of the *de facto* partnership and simplified the rules about the creation and the functioning of the limited liability company with a single shareholder (*société unipersonnelle*) to offer a wider range of opportunities to African people willing to join for a business endeavour and to provide solutions better tailored to the peculiarities of doing business in the African context[54].

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[51] Art. 30, par. 7, AUDCG.

[52] J. Issa-Sayegh, *L'entreprenant* cit.

[53] See Title II, Chapter II, Section 4 of the Uniform Act of Bankruptcy, revised version (2015), Articles 24 to 24-5.

[54] See more on this in S. Kwemo, *L'OHADA* cit.

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In practical terms, however, the impact of these changes on the informal commerce has been minimal up to now: very few informal entrepreneurs decided to become *entreprenant*, and the other new rules introduced have been scarcely applied[55].

OHADA's attempt to find a solution for the issues of informal commerce is surely praiseworthy, but the unavoidable vagueness of the rules provided clearly shows how difficult it is for the law to deal with the flexible and "slippery" institutions of the informal sector.

4. A different way forward

The discussion made above shows that all attempts made to bring formal law near the informal sector follow the same path: to make to formal law those changes deemed necessary to facilitate the migration of the informal businesses to the formal sector. In other words, up to now the discussion has been on how to adapt formal law to match the needs of the informal sector, that is bringing formal law to the informal sector.

As previously seen, the results obtained are not encouraging. The introduction of the Western pattern determined the implementation of a strongly positivist system in the OHADA region, which is antithetic to the flexibility of the African pattern. The OHADA system possibly answers the needs arising from globalization and promotion of foreign investments, but it is definitely far from the daily legal needs of the ordinary people. Paradoxically, OHADA law is more easily accessible to people (that most likely do not have the necessary skills to understand it) than the rules governing the informal sectors of the different member countries (more familiar to

[55] A. Aly Mbaye, S. S. Golub, and F. Gueye (eds.), *Formal and Informal Enterprises in Francophone Africa: Moving Toward a Vibrant Private Sector*, (IDRC 2020); S. Bissaloue, *L'informel* cit.; P. Winship, 'Law and Development in West and Central Africa (OHADA)', (2015), SMU Dedman School of Law Legal Studies Research Paper No. 272 available at https://scholar.smu.edu/cgi/viewcontent.cgi?article=1197&context=law_faculty. See also The World Bank/IFC, "An Impact Assessment of OHADA Reforms", (2018), available at https://documents1.worldbank.org/curated/en/591171552538874508/pdf/135279-12-3-2019-18-19-19-EnglishOHADAICImpactFinalReport.pdf.

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the ordinary people). In such a positivist context, it is not surprising that informal rules struggle to find in the official law the place they have in the daily life of people, that we do not find any reference to them in the OHADA jurisprudence, and that very seldom scholars consider them when discussing about OHADA laws and their application[56].

Then, taking into consideration the scarce results achieved, it is maybe necessary to consider a different perspective and investigate on how to integrate the informal normative order regulating the informal sector into the official law.

This kind of approach necessarily requires a reconsideration of the entire discourse of legal pluralism in Africa.

The concept of legal pluralism has been admirably described by Jacques Vanderlinden as "…une situation dans laquelle un individu se trouve au carrefour de plusieurs ordres juridiques et oriente par son choix la solution à donner à un conflit éventuel tant du point de vue du for compétent que du droit applicable. […] Quel que soit le choix qu'il fasse, il risque d'entrer en conflit avec l'un, voire plusieurs, des réseaux dont il aura refusé de reconnaître le prescrit"[57], determines a conflictual relationship between the different normative orders that come into competition, in which one – the official law – tries to affirm its predominant role, and the others – the unofficial or informal laws – continuously challenge it. In any case, the different regulatory orders are in competition with each other, and, following such definition of legal pluralism by Jacques Vanderlinden, one normative order tends to exclude the other.

What, then, could the next step be?

The next step could (and should) be the one in which the conflictual relationship is replaced by a collaborative relationship between the various legal orders so that they can complete each other or at least not compete with each other.

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56 O. Ballal, *Les usages* cit., at 81.

57 J. Vanderlinden, 'Villes africaines et pluralisme juridique', (1998) 42 Journal of Legal Pluralism and Unofficial Law, 245.

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We are already aware of the impossibility of forcedly eliminating the African legal tradition: it is too strong and too rooted in the people, even those who live in cities and apply Western life models. Is it therefore possible to hypothesize a cooperation between these normative orders? It could be objected that collaboration is not actually possible, because the application of a legal order necessarily excludes the application of others. But this is not necessarily true, and many examples could be made in this direction[58].

Collaboration can be based on a hierarchical relationship (of supremacy) or equality. The first is the model based on the primacy of the source of Western derivation. Experience tells us that this last approach does not pay, and that equal dignity must be recognized for different normative orders. On the other hand, it is claimed that at least one *grundnorm* is necessary to dictate the basic rules of this cohabitation. But again, it can be objected that the very idea of the *grundnorm* is also of Western derivation and alien to the African legal culture more suited to a circumstantial and not to a predetermined approach.

And then? Make the *grundnorm* permeated with the local legal culture along with the principles of the European model? Coexistence to dictate the rules of coexistence?

The hypothesis is not strange. In the Somaliland constitution, the Senate (called in the constitution *House of Guurti*, or *Goolaha Guurtida* in Somali) is nothing but the institutionalization of the council of elders at the constitutional level. The *House of Guurti* deals with the resolution of inter-clan conflicts through a constant connection with local elders, leaving the elders the task of resolving the dispute every time the Lower Chamber is unable to do so, always having mediation and peacekeeping as primary goals. It therefore constitutes a sort of representation of the elders in the capital city. It also performs a central role of mediation between the government and the parliament: it reviews all the laws (with the exception of the financial ones) approved by the parliament and can block the enactment or request changes whenever the laws are considered contrary to the culture or interests of the

58 See more in S. Mancuso, 'Pluralismo e ordini normativi in Africa. Dal conflitto alla collaborazione', in M. Graziadei, M. Serio (eds.), *Regolare la complessità. Giornate di studio in onore di Antonio Gambaro*, (Giappichelli 2017).

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population; it also has legislative competence on religious, cultural and security issues[59].

Moving to the OHADA level, a preliminary – but fundamental – choice needs to be made clear: if the OHADA system has been created to regulate only transactions involving big businesses and multinational corporations, or (as it appears from the way the system is conceived) if the system is has been conceived to offer to all people living and operating in the member countries a more modern and effective system of business law.

If the latter is the correct direction, then the African legal culture cannot be ignored and the principles of informal law governing the informal sector shall necessarily be part of the system governing business transactions together with those imported through the use of the Western pattern.

I already proposed this approach when discussing the way forward for the possible harmonization of contract law in the OHADA system[60]. The methodological approach proposed there intends to conduct research to verify the existence of common principles in traditional contract law within the OHADA region, a sort of "common core of African informal contract law", that could inspire the OHADA legislator in his work on harmonization of contract laws. Then the research could also be expanded to all relevant aspects of informal rules governing business law in the OHADA context.

The main objection to an approach like the present one is perhaps the wide legal diversity existing in the OHADA region in the ambit of the informal sector. Nevertheless, despite the diversity of the African continent and of its legal facets, we must take into account the general and clear resemblances existing among the different African legal cultures as revealed by the authors who conducted analytical

59 S. Mancuso, 'Short Notes on the Legal Pluralism(s) in Somaliland', in S. P. Donlan, Lukas Heckendorn Urscheler (eds.), *Concepts of Law*, (Ashgate, 2014, 237)

60 S. Mancuso, 'Le droit OHADA vers sa population. Y-a-t' il une place pour les droits originellement africains dans le processus d'harmonisation du droit des contrats en Afrique?', in *Les pratiques contractuelles d'affaires et les processus d'harmonisation dans les espaces régionaux*, (conference proceedings), (2012) Porto Novo, ERSUMA.

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field studies across the continent, since they present always and everywhere the same essential characteristics[61].

Inserting principles derived from the rules governing the informal sector is not against the OHADA law. Other than Article 177 of the AUDCG that opens to the validity of usages normally practiced in agency relations, Article 239 of the same AUDCG expressly provides – with reference to the commercial sale – that the parties to a contract are bound by the usages to which they consented and by the practices established in their commercial relations, as well as by the professional usages largely known and regularly observed in the same commercial sector that they know or should have known, unless differently agreed. Moreover, according the following Article 240 there is no formal requirement to enter into a commercial sale contract that can be written or oral and that can be proved by any means.

The need to take into account African specificities was also a concern raised during the preparation and discussion of the first preliminary draft of the Uniform Act on Contract Law, drafted by Marcel Fontaine[62]. He inserted a principle almost identical to those of the AUDCG mentioned above in Article 1/8 of the draft Uniform Act, by providing that the parties to a contract are bound by the usages to which they consented and by the practices established between them, as well as by the usages largely known and regularly observed by the parties in contracts of the same kind, unless their application is unreasonable. There, one of the guiding principles in drafting the uniform act was to take into account the unique African features of contract law and he raised the issue if these unique African features should refer to traditional contract law. However, he observed that "[w]hile there still exist native rules that govern local contractual relationships, these are certainly not widely

61 T. Olawale Elias, *The Nature of African Customary Law*, (Manchester University Press 1956).

62 The discussion of the draft proposal has reached its higher academic level during the Colloquium held in Ougadougou on 15-17 November 2007. The presentations were published in 2008 in the Uniform Law Review vol. XIII, n.1/2. On the need to take into consideration African realities, see also G. Kenfack Douajni, 'La coordination de l'avant-projet d'Acte uniforme sur le droit des contrats avec les autres Actes uniformes de l'OHADA', (2008) 13 (1/2) Revue de droit uniforme/Uniform Law Review, 367.

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known"[63], and "[i]t is nevertheless important to take into account the African specificities in order to make the necessary adaptations. Everyone has evidently agreed. However, my interlocutors have experienced many difficulties in identifying the specific characteristics of contract law, which would be common to the region, if not the generally high degree of illiteracy"[64].

This kind of openings are the best vehicle to facilitate the insertion of informal rules into the system if there is the willingness to do so. This would definitely help to cope with the issue of illiteracy still largely present in sub-Saharan Africa, while the possibility to merge the application of formal and informal rules could help the actors of the informal sector in having a better knowledge of the formal rules too and to feel more confidence in the system governing their activities.

Finding the common principles of informal business law in the OHADA region (and maybe beyond, if we take into consideration the possible future enlargement of OHADA membership) would also be in line with the basic requirements indicated in the above-mentioned Articles of the AUDCG for the validity of the usages to be complied with. Indeed, the usages (or the informal practices) must be "largely known" and "regularly observed"[65]: it is evident how legal principles deriving from informal commercial activities which are common and shared by the informal entrepreneurs across the OHADA region can easily comply with the requirements of large knowledge and regular observation mentioned above.

These introductory methodological remarks need to touch upon the issue of dispute resolution in order to be complete.

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63 M. Fontaine, 'The Draft OHADA Uniform Act on Contracts and the UNIDROIT Principles of International Commercial Contracts', (2004) 9 (3), Revue de droit uniforme/Uniform Law Review, 573, at 578.

64 M. Fontaine, 'L'avant-projet d'acte uniforme OHADA sur le droit des contrats: vue d'ensemble', (2008) 13 (1/2) Revue de droit uniforme/Uniform Law Review, 204. The adaptations to which Marcel Fontaine refers are to the UNIDROIT principles of international commercial contracts, on which the first draft Uniform Act on Contract Law was based.

65 See Articles 177 and 239 par. 2 AUDCG. For a wide description of these two requisites see O. Ballal, *Les usages* cit., at 133 and ff.

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As briefly seen above, disputes in the informal sector may not be settled by the official State courts but the contractual parties may prefer to resort to the informal courts, often belonging to the same informal realities, otherwise they report the issue to the police.

The recently approved Uniform Act on Mediation could help in this respect. The Uniform Act defines mediation as "[…] any process, whatever the name, in which the parties request a third party to assist them in reaching an amicable settlement of a dispute, a conflicting relationship or a disagreement […] arising from a legal, contractual or other relationship or linked to such relationship, involving natural or legal persons, including public entities or the State". Mediation can be implemented by the parties (conventional mediation), at the request or invitation of a state court (judicial mediation), an arbitral tribunal or a competent public entity[66]. There are no procedural requirements to conduct the mediation, and if there is no specific requirement by the parties, the mediator conducts the mediation as he deems appropriate[67]. If, at the end of the mediation, the parties conclude a written agreement settling their dispute, this agreement is binding for them; such agreement resulting from the mediation can be enforced using the official judicial channels[68].

Looking at these basic principles we can surely affirm that the settlement of disputes arising from the informal courts can be incorporated into the formal system using the mediation channel, as they match the fundamental requirements to have a mediation as indicated above. We have already observed how the "informal sanctions" (enlarged liability at familial or community level, distrust, ostracism from the business community) already represent a strong deterrent to the non -fulfilment of the contractual obligations or the decisions of the informal courts, but the possibility to insert these latter in the official system using the mediation channel will also offer the official enforcement measures as further remedy: this would also be a way to help actors of the informal sector to approach the legal instruments offered by the formal channel.

66 Art. 1 AUM.

67 Art. 7 AUM.

68 Art. 16 AUM.

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Being a public authority (a public entity, according to Art. 1 AUM), the police – if requested for an intervention – could even act as a mediator to the extent that the basic requirements of the Uniform Act are respected (it shouldn't be difficult as the police is supposed to know the law…); otherwise it should encourage the parties to resort to a mediation where the mediator can even be an elder, the chief of the market or the informal court in the market, as the term "mediator" indicates any third party solicited to mediate a dispute, no matter what is the name or occupation of the third party in the State Party concerned[69].

To conclude, there are several aspects that could be explored in order to approximate OHADA and the rules governing the informal sector, provided that there is the intention to change how such approximation shall be done. A key step in this direction is to acknowledge the existence of legal pluralism in the African legal reality and to reconsider it: this means that insisting on the exclusive monopoly of the State in the law-making process would not lead to any result and that it is necessary to admit that these different normative orders shall be considered not anymore competing but cooperating to create a system that is more easily manageable and usable by the people.

69 Art. 1 (b) AUM.

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Towards a Digital Ecosystem of Trust: Ethical, Legal and Societal Implications

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Abstract

The European vision of a digital ecosystem of trust rests on innovation, powerful technological solutions, a comprehensive regulatory framework and respect for the core values and principles of ethics. Innovation in the digital domain strongly relies on data, as has become obvious during the current pandemic. Successful data science, especially where health data are concerned, necessitates establishing a framework where data subjects can feel safe to share their data. In this paper, methods for facilitating data sharing, privacy-preserving technologies, decentralization, data altruism, as well as the interplay between the Data Governance Act and the GDPR, are presented and discussed by reference to use cases from the largest pan-European social science data research project, SoBigData++. In doing so, we argue that

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innovation can be turned into *responsible* innovation and Europe can make its ethics work in digital practice.

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Keywords

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Digital ecosystem of trust – responsible data science – data altruism – decentralization.

1. Introduction

Europe has developed ambitious plans for its digital leadership in the remainder of the 21th century. With the 2016 EU 'General Data Protection Regulation' (GDPR) and new plans for a Data Governance Act (DGA) and new Regulation for Artificial Intelligence (AI Regulation), the European Union hopes to set global standards for the Digital Age on the basis of its law. The EU has introduced the new model of trustworthy digital environment in an attempt to create an adequate alternative to the existing developments, characterized by a data-centric approach, exclusive IP schemes and data commercialization practiced by large technological companies. The DGA, meant as a centerpiece to the European data sharing framework, promises to foster the availability of data for use, but also promote trust in data intermediaries, technology and strengthening data-sharing mechanisms across the EU. A trustworthy environment requires instruments able to ensure that data from the public sector, industry and citizens is available for use in the most effective and responsible manner, while citizens retain a reasonable degree of control over the processing of data they generate, and businesses can rely on adequate protection of their investments in data economy.[1] The EU has rightly foregrounded ethical principles and fundamental rights, since they are enshrined in its constitutive and binding treaties. On this basis, it aims at building a European digital ecosystem of trust and excellence that will allow the EU to make the best possible use of the potential of Digital Innovations to help solve grand societal challenges. There is however a recurrent concern in Europe itself and a point of surprise, or even disbelief, outside Europe: how can one prosper in a digital economy, how can one lead digital innovation and spearhead data-driven research and AI development while being firmly committed to the highest ethical standards, especially when others are not.

This paper seeks solutions to this challenge. In doing so, it draws upon the findings, results and experience in the SoBigData++ research environment, comprising over

[1] DGA, Explanatory Memorandum.

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thirty research institutions, spread across thirteen countries, united by the goal of establishing a pan-European research infrastructure (RI) for social science big data. An important part of the response to the above concern has to do with the fact that this approach fosters trust and augments the quality of relevant institutions. Trust and the quality of institutions are a key determinant in the success of nations[2] and therefore a key to successful digital societies. Trust is at the same time an elusive moral concept. With regard to trust in the context of state power, law and trust cannot be separated and both serve as mechanisms to reduce complexity and risk.[3] Trust implies the belief that the trusted are well-intentioned and are taking a moral view. Like friendship, trust cannot be produced at will and those who set out to 'manage' our trust in relations may find their attempts to be counterproductive. Trust usually does not appear in one's Excel sheets, but when there is no trust, the costs associated with (re-)establishing it become evident. Trust in the digital economy requires infrastructures, institutions, mechanisms and habits to be in place that allow people to receive reliable signals of the moral quality of intentions and plans of others, so that they can determine whether trust or distrust is the appropriate attitude in their interactions. All the above requires a continuous nurturing of awareness about the issues for which trust is needed and embedding this in the culture of organizations.

We define a digital ecosystem of trust as a system of interacting organisms and their environment,[4] in which appropriate norms are clear to parties, and responsibilities are well defined and adequately and fairly allocated to actors and agents. Trust needs to be horizontal between citizens and parties and also vertical between citizens and governments. The SoBigData++ project provides examples of designing for trust in big data ecosystems by furthering (i) data altruism and generosity, (ii) practices of responsible data science, (iii) responsible innovations for privacy-respecting technologies, (iv) research integrity review boards in AI and data-driven research, (v) adequate governance schemes. In this way, both primary and

[2] D. Acemoglu, J. A. Robinson, *Why Nations Fail* (Profile Books 2012).

[3] N. Luhmann, *Trust and Power* (John Wiley and Sons 1979).

[4] The Oxford English Dictionary (Oxford University Press 2003, 5th ed).

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secondary use of data can be responsibly geared towards big data and data analytics for the general good of all.

The core aim of this paper is to discuss Europe's plans to profile itself as promoter of ethics and values with the aim to create a digital ecosystem of trust where, on the one hand, people feel safe to share their data and, data science and analytics (either primary or secondary) are conducted with due respect for the subjects' rights while on the other hand the digital functionality can be deployed when and where it can be deployed productively to solve our problems. This is connected to the central questions: *What conditions need to be fulfilled for people to trust an ecosystem in which they would feel safe to share their data? How may one build an appropriate research infrastructure for data science - a prototype of an ecosystem of trust?*

In principle, trust in digital ecosystems is formed from a variety of aspects, not only of legal or technical nature, but also addressing data governance, such as who uses the technology and how the technology is used. Each instrument may reveal benefits and disadvantages depending on the perspective of the actor: citizens, governments, science or businesses. Each solution can be supported by diverse arguments. This paper does not offer an objective analysis of suggested solutions, rather it presents a broad overview of many aspects related to trust in digital ecosystems. The instruments introduced by the European legislative initiatives are tested in their efficiency to counteract the tendencies of centralization and exclusive IP arrangements. The work is based on technical legal and normative analysis.

In order to address this central question in an innovative way, the paper adopts the following structure. Next, we look at privacy-preserving technologies in their pros and contras with respect to data control (Section 2), supplemented with use cases from the SoBigData++ project. We continue with novelties of data sovereignty, data altruism, decentralization and data intermediaries introduced by the Data Governance Act (DGA) (Section 3). This is followed by a consideration of the interplay between the DGA and the GDPR, as well as the GDPR's intricacies for research (Section 4). The paper then concludes by considering some desirable steps for the future (Section 5).

2. New privacy-respecting technologies

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It is sometimes argued that Europe's strong regulations on privacy hamper the scientific and economic progress that could ensue from massive data collection and processing.[5] While eliminating all barriers would no doubt facilitate progress in certain directions, the issue deserves more careful consideration.

On the one hand, unlimited collection and processing of personal data conflicts with fundamental rights and ethical values such as privacy, autonomy, fairness and security.[6] On the other hand, the need to reconcile progress with the aforementioned rights and values spurs technology research, innovation and development.[7]

Privacy-preserving technologies are the workhorse that enforces the protection of digital assets, whether they are personal or corporate.[8] In particular, such technologies are instrumental to implement privacy and data protection by design. Due to its legal framework and its expertise in information technologies, Europe is very well placed to take the lead in innovation on privacy-preserving technologies and establish a common understanding of digital society notions across disciplines.[9] We next sketch directions that hold promise.

Right now, a very common setting in privacy preservation is to rely on trusted third parties (certification authorities, data controllers that take care of anonymizing or encrypting data, etc.). The trend of future information technologies is to follow the

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[5] R. Eiss 'Confusion over Europe's data-protection law is stalling scientific progress' (2020) Nature 484; contra, see G. Schneider, G. Comandè 'Differential Data Protection Regimes in Data-driven Research: Why the GDPR is More Research-friendly Than You Think' (2021, forthcoming) German Law Journal.

[6] J. Domingo-Ferrer, A. Blanco-Justicia 'Ethical value-centric cybersecurity: a methodology based on a value graph' (2020) 26 3 Science and Engineering Ethics 1267.

[7] G Schneider, G Comandè, 'Can the GDPR Make Data Flow for Research Easier? Yes it Can! By Differentiating!', (2021) 41 Computer Law & Security Review 105539.

[8] G Danezis, J Domingo-Ferrer, M Hansen, J. H. Hoepman, D. Le Métayer, R. Tirtea, S. Schiffner, 'Privacy and Data Protection by Design – from Policy to Engineering' (2015) European Union Agency for Network and Information Security (ENISA).

[9] G. Comandé (ed.), *Elgar Encyclopedia of Law and Data Science* (Edward Elgar 2022).

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ethics-by-design approach, which inherently reduces the need for trust by empowering individual users. This is substantiated by the following design principles:

- *Decentralization*. Most individuals currently have powerful personal computing devices (smartphones, tablets, etc.). Hence, it is possible for them to carry out a fair amount of computation. This has resulted in new paradigms for decentralized machine learning (federated learning,[10] fully decentralized learning,[11] etc.), for decentralized, local anonymization,[12] for decentralized COVID-19 contact tracing, etc.

- *Incentivization*. Decentralized computing relies on the willingness of individual participants to play their respective roles as specified in the computation protocols. But this cannot be taken for granted. Without proper incentives, a rational participant might be better off by not joining the protocol, or by deviating from it, free-riding it or dropping it. The poor uptake of COVID-19 contact tracing apps in spite of most of them being privacy-preserving is a recent example of what can happen when incentives are lacking:[13] people do not feel very motivated to install and run an app that can only give them negative (and maybe false) news. Offering additional services might be a better way to follow.[14]

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[10] H. B. McMahan, E. Moore, D. Ramage, D. Hampson, B. Agüera 'Communication-efficient learning of deep networks from decentralized data' (2017) Proc. of the 20th Intl. Conf. on Artificial Intelligence and Statistics – AISTATS'2017 1273.

[11] A. Koloskova, S. Stich, M. Jaggi 'Decentralized stochastic optimization and gossip algorithms with compressed communication' (2019) Proc. Of the 36rd International Conference on Machine Learning – ICML 2019 3478.

[12] J Domingo-Ferrer, J Soria-Comas 'Multi-dimensional randomized response' (2021, forthcoming) *IEEE Transactions on Knowledge and Data Engineering*.

[13] S. Toussaert 'Upping uptake of COVID contact tracing apps' (2021) 5 Nature Human Behaviour 183.

[14] M. Nanni, G. Andrienko, AL. Barabási, et al. 'Give more data, awareness and control to individual citizens, and they will help COVID-19 containment' (2021) Ethics Inf Technol.

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In behavioral economics, it has long been known that moral behavior can be encouraged and incentivized.[15] In decentralized computing, the co-utility approach[16] follows this idea by designing protocols in such a way that adhering to them is the best option for all participants: in game-theoretic terms, following a co-utile protocol as specified is an equilibrium for all participants.

Crafting decentralized, co-utile protocols allows embedding not only privacy preservation, but virtually any ethical values by design. This is open ground for European academia and industry to conquer and cultivate. If this opportunity is properly seized, an "*IT made in Europe*" seal might become synonymous with ethics-compliant technology. Ethics by design, as discussed in the AI Regulation, should signal that the development and use of technology (in particular AI) are guided by certain essential value-oriented principles. The core principles of data protection are embedded into technology by virtue of data protection by design (Article 25 GDPR). Alike, transparency and protection against unfair commercial practices may find reflection in ethics-oriented technology (as envisaged by the AI Regulation). Software can be viewed as set of rules whereby machines act. And these rules can embed ethical principles. For example, as follows from the literature on anti-discrimination: artificial intelligence can be trained with more or less biases. A downside is that amid the flourishing field of data analytics, the implementation of the said principles on the level of the law may encounter opposition from the data industry. However, beyond a pay-off in moral and legal terms, this could also give a new purpose and competitive strength to the European IT industry.

2.1 Ethics-integrating approaches proposed by the SoBigData++ project

The focal point of this paper is on building trust, mainly focusing on privacy, data protection, and data management. We will briefly review the various solutions, which are currently in different progress statuses, i.e., in the developing phase or near to

[15] B. S. Frey, F. Oberholzer-Gee 'The cost of price incentives: an empirical analysis of motivation crowding-out' (1997) 87 4 The American Economic Review 746.

[16] J. Domingo-Ferrer, A. Blanco-Justicia, D. Sánchez, N. Jebreel 'Co-utile peer-to-peer decentralized computing' (2020) 20th IEEE/ACM International Symposium on Cluster, Cloud and Internet Computing – CCGrid 31.

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being published in the SoBigData++ Catalogue. A detailed study on these topics will be provided in the following White Papers.

Firstly, an analytical platform cannot be considered ethical without non-discrimination guarantees. Indeed, AI models can amplify existing biases coded in data or introduce new forms of bias,[17] resulting in discriminatory or unfair decisions. Approaches to tackle the problem of algorithmic fairness have been proposed within different fields. In the SoBigData++ consortium, we rely on auditing AI-based systems for discrimination discovery[18], through published libraries such as "dd: a Java library for discrimination discovery and sanitization". The final desirable objective is to embed the fairness value in the design of AI models (fairness-by-design).

A second, essential aspect to be tackled concerns the use of social media and social media analysis. Here, the issues of misinformation, fake news, and polarization have become more and more central. In SoBigData++, we dealt with the problems of bot detection,[19] useful to detect automatically a new generation of increasingly technologically advanced spambots, and polarization and echo chambers,[20] which drive debates and increase discords and conflicts. A possible countermeasure to these

[17] A. Olteanu, C. Castillo, F. Diaz, E. Kiciman 'Social Data: Biases, Methodological Pitfalls, and Ethical Boundaries' (2019) Frontiers Big Data 2.

[18] A. Romei, S. Ruggieri 'A multidisciplinary survey on discrimination analysis' (2014) 29 5 Knowledge Eng Review 582; S. Ruggieri 'Using t-closeness anonymity to control for non-discrimination' (2014) 7 2 Transactions on Data Privacy 99.

[19] S. Cresci, R. Di Pietro, M. Petrocchi, A. Spognardi, M. Tesconi 'The paradigm-shift of social spambots: Evidence, theories, and tools for the arms race' (2017) Proceedings of the 26th international conference on world wide web companion; S. Cresci, R. Di Pietro, M. Petrocchi,A. Spognardi, M. Tesconi 'DNA-inspired online behavioral modeling and its application to spambot detection' (2016) 5 31 IEEE Intelligent Systems 58.

[20] V Morini, L. Pollacci, G. Rossetti 'Toward a Standard Approach for Echo Chamber Detection: Reddit Case Study' (2021) 11 12 Applied Sciences 5390; V. Morini, L. Pollacci, G. Rossetti 'Capturing political polarization of Reddit submissions in the Trump Era' (2020) 28th Symposium on Advanced Database Systems; A. Sîrbu, D. Pedreschi, F. Giannotti, J. Kertész 'Algorithmic bias amplifies opinion fragmentation and polarization: A bounded confidence model' (2019) 14 3 PloS one.

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problems is to deeply analyze the phenomena of misinformation and disinformation[21] and understand diffusion mechanisms over complex networks.[22]

Finally, another ethical dimension is explainability, which is useful at the development level since it permits to understand and possibly discover undesired behavior within the reasoning of AI methods. Even if full transparency and interpretability are the most powerful solutions,[23] they can also be challenging to reach. Thus, we believe that also meaningful explanations of black-box decision systems can be useful in many cases.[24] These explanations can be related to the whole AI model or to specific instances, and also the kinds of the given explanations depend on several variables, such as the kind of data, the context, and the person to whom the explanation is delivered.[25] A collection of explainability methods will be provided within the SoBigData++ Catalogue.[26]

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[21] K. Bontcheva, J. Posetti, D. Teyssou, T. Meyer, S. Gregory, C. Hanot, D. Maynard 'Balancing act: Countering digital disinformation while respecting freedom of expression' (2020) United Nations Educational, Scientific and Cultural Organization; X. Song, J. Petrak, Y. Jiang, I. Singh, D. Maynard, K. Bontcheva 'Classification aware neural topic model for COVID-19 disinformation categorisation' (2021) 16 2 PloS one.

[22] See http://data.d4science.org/ctlg/ResourceCatalogue/ndlib. L. Milli 'Opinion Dynamic Modeling of News Perception' (2021) 6 1 Applied Network Science 1; G. Rossetti, L. Milli, S. Rinzivillo, A. Sîrbu, D. Pedreschi, F. Giannotti 'NDlib: a python library to model and analyze diffusion processes over complex networks' (2018) 5 1 International Journal of Data Science and Analytics.

[23] C. Rudin 'Stop explaining black box machine learning models for high stakes decisions and use interpretable models instead' (2019) 1 5 Nature Machine Intelligence 206.

[24] F. Bodria, F. Giannotti, R. Guidotti, F. Naretto, D. Pedreschi, S. Rinzivilli 'Benchmarking and Survey of Explanation Methods for Black Box Models' (2021) CoRR abs/2102.13076; R. Guidotti, A. Monreale, F. Giannotti, D. Pedreschi, S. Ruggieri, F. Turini 'Factual and counterfactual explanations for black box decision' (2019) 34 6 making IEEE Intelligent Systems 14.

[25] R. Guidotti, A. Monreale, S. Ruggieri, F. Turini, F. Giannotti, D. Pedreschi 'A survey of methods for explaining black box models' (2018)51 5 ACM computing surveys 1.

[26] See <https://data.d4science.org/ctlg/ResourceCatalogue/xai_method_for_explaining_time-series>. Accessed 21 Dec 2021.

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Drawing upon concrete cases and examples within the SoBigData++ project - namely mechanisms in play to address data-related issues – helps to show how the above-mentioned aims may be realized in practice.

The SoBigData and SoBigData++ projects[27] have developed a few vertical, thematic environments, called *exploratories*, focused on specific contexts and research questions. They are intended to test the effectiveness of the cross-disciplinary social mining research conducted on top of the SoBigData research infrastructure. The core exploratories are as follows:

- *Sustainable Cities for Citizens*: models and patterns extracted from data about cities and people living in them serve to generate knowledge about urban mobility, of potential use for local administrators to improve their services and the overall quality of living.

- *Societal Debates and Misinformation Analysis*: the analysis of discussions on social media allows understanding public debates and opinion, tracking them through time and space, and investigating the widespread phenomena of misinformation and bias.

- *Demography, Economy & Finance 2.0*: data of supermarket purchases, of people's mobility, and of financial transactions, allow the investigation of the changes in the well-being of people and in the network structure of companies due to the economic crisis.

- *Migration Studies*: the phenomenon of international migration is studied with models extracted from big data (mobile phone data, social media, surveys, official statistics, etc.), including economic models of migration, visualizing migration flows and stocks, identifying perception of migration, understanding cultural diversity and integration.

- *Sports Data Science*: starting from massive data describing several sports (especially soccer, cycling and rugby) interpretable and easy-to-use models of player performances are offered to practitioners, fans, coaches, and managers.

[27] See <https://plusplus.sobigdata.eu/>. Accessed 21 Dec 2021.

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Let us focus on *Sustainable Cities for Citizens* as a representative example challenging the digital ecosystem of trust offered by the research infrastructure. Data about people's mobility[28] can be collected from mobile phones, vehicle trajectories, geolocated content uploaded to social media, travel tickets and cards, vehicle sharing services (bikes, scooters, cars, etc.), traffic volumes road sensors, video and photograph streams of security cameras, satellite images, credit card transaction data, shopping records, wi-fi connection, etc. Several useful initiatives and services for citizens and the public-policy decision makers can be designed using models of human behavior extracted from such big data: optimizing mobility and location-based services (car sharing, tour recommendation, public transportation scheduling); supporting urban sustainability through the understanding of urban social activities highlighted by extracted models; planning for different profiles of city users (residents, commuters, visitors, disabled, poor) whose behavior is characterized by those models; optimizing resource distribution (residential energy management, load balancing of shared bikes) based on data-driven analyses and simulations.

The downside is that data collection and models/services may put the privacy of people at risk, e.g., they may disclose the sensitive position of an individual.[29] The trade-off here is to balance the utility of the discovered mobility patterns against the necessary privacy safeguards.[30] Methods offered by the SoBigData platform are applicable at different stages of the data analysis process. Data can be perturbed or

[28] G. L. Andrienko, N. V. Andrienko, C. Boldrini, G. Caldarelli, P. Cintia, S. Cresci, A. Facchini, F. Giannotti, A. Gionis, R. Guidotti, M. Mathioudakis, C. I. Muntean, L. Pappalardo, D. Pedreschi, E. Pournaras, F. Pratesi, M. Tesconi, R. Trasarti '(So) Big Data and the transformation of the city' (2021) 11 4 Int. J. Data Sci. Anal. 311.

[29] A. Bonavita, G. Comandé, 'Mobility Data (Knowledge Discovery from)', in G. Comandé (ed.) *Elgar Encyclopedia of Law and Data Science* (Edward Elgar 2022), 227 ff.

[30] T Asikis, E. Pournaras 'Optimization of privacy-utility trade-offs under informational self-determination' (2020) 109 Future Generation Computer Systems 488; F. Pratesi, A. Monreale, R. Trasarti, F. Giannotti, D. Pedreschi, T. Yanagihara 'PRUDEnce: a System for Assessing Privacy Risk vs Utility in Data Sharing Ecosystems' (2018) 11 2 Trans Data Priv 139.

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aggregated to obfuscate individual information.[31] Private-by-design methods[32] are offered to account for privacy risks when disclosing discovered patterns and models. Finally, privacy risk estimators support the data analyst to quantify and monitor the risk of re-identification from individual mobility patterns[33] and from mobility profiles.[34] The platform also offers general mechanisms to tag data with meta-information for ease of search, to control access to data and methods, and to run methods on the cloud.

In summary, the maturity of tools from the literature on privacy-preservation is a prerequisite for the ethics-oriented technology to be accepted and trusted. The *Sustainable Cities for Citizens* exploratory is a significant example showing how the privacy of data subjects and the utility of models extracted from those data can be dealt with at the same level of importance in the design of individual and society-wide data-driven services. Adequate implementation of such tools relies on expert knowledge and skills, requiring investments. While thus not necessarily an immediate advantage (from economic perspective). However, besides being justified by considerations of compliance, data citizens share under conditions of trust may be expected to have greater accuracy and utility in the long term.

3. Data Sovereignty and data altruism fostered by the DGA

A significant step towards decentralization of the web and de-monopolization of data is expected to be achieved under the Data Governance Act. The DGA's aim is to

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[31] M. Fiore, P. Katsikouli, E. Zavou, M. Cunche, F. Fessant, D. Le Hello, U. Matchi Aïvodji, B. Olivier, T. Quertier, R. Stanica 'Privacy in trajectory micro-data publishing: a survey' (2020) 13 2 Trans. Data Priv. 91.

[32] N. V. Andrienko, G. L. Andrienko, G. Fuchs, P. Jankowski (2016). Scalable and privacy-respectful interactive discovery of place semantics from human mobility traces. Inf. Vis. 15(2): 117-153.

[33] R. Pellungrini, L. Pappalardo, F. Pratesi, A. Monreale 'A Data Mining Approach to Assess Privacy Risk in Human Mobility Data' (2018) 9 3 31 ACM Trans. Intell. Syst. Technol. 1.

[34] F. Pratesi, L. Gabrielli, P. Cintia, A. Monreale, F. Giannotti 'PRIMULE: Privacy risk mitigation for user profiles' (2020) 125 Data Knowl. Eng. 101786.

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create a regulatory framework to facilitate data sharing, *inter alia* in support of data science and open innovation, and to foster altruistic uses of personal and non-personal data. This approach suggests an attempt by the legislator to react to the situation that society requires protection in the context of who uses technology and how technology is used.

The proposed DGA introduces information intermediaries to replace big tech players, encourages 'data altruism' with citizens to facilitate data sharing, and opens avenues for self-sovereign identities.

3.1. From data monopolies to data commons

As our societies are dealing with the social and economic implications of the Covid-19 pandemic and the reconfigurations they entail, the opportunity seems to present itself to "reclaim" digital services and data from centralized monopolies, and for practices of "data altruism". This underscores the importance and potential of initiatives with the objective of building a digital environment that encourages trust. We will provide a brief overview of some of these initiatives, which are also addressed by Dulong de Rosnay and Musiani:[35]

- In a number of contexts where AI dynamics are present, such as "smart cities" and "algorithmic governance", citizen data can either be managed in a top-down fashion,a nd controlled by centralized "control points";[36] or, alternatively, as a commons. This alternative is about the amount and quality of control and opportunities for citizen re-appropriation of data, as well as the ability to promote data commons governance models, opposed to exclusive intellectual property arrangements.

[35] M. Dulong de Rosnay, F. Musiani, 2020, "Alternatives for the Internet: A Journey into Decentralised Network Architectures and Information Commons", tripleC: communication, capitalism & critique, vol. 18, no 2, p. 622-629.

[36] L. De Nardis *The Global War for Internet Governance* (2014 Yale University Press).

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- Citizens co-produce and release, intentionally or not, several types and sets of data on a daily basis, for example, by using municipal digital services. These data can be governed in a democratic, consensus-based or collegial manner, as urban or data commons, which might avert or at least mitigate the risk to turn smart cities into dystopian 'safe cities', having surveillance capitalism dynamics at their core.

- A number of other projects generate what has been defined as "big data": e.g. open data on public transportation,[37] P2P energy production by means of decentralized networks,[38] Internet of Things captors that measure street pollution rates in the frame of participatory science initiatives, or smart devices aimed at monitoring our health signs in the frame of what Andrea Matwyshyn has called the "Internet of Bodies".[39] These big data-fuelled dynamics are at a crossroads: if kept open, they can be useful and directly re-usable as a basis for policy decisions and scientific research.

- We should however keep in mind that these data include sensitive personal information in need of safeguards, such as location or health data. As we have argued elsewhere[40] privacy and commons may at first glance appear as incompatible or only partially interoperable. However, proposals do exist to apply the analytical framework of knowledge commons to private data. In these models, personal data are understood as contextualized personal information flow.[41]

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[37] M. Teli, S. Bordin, M. Menéndez Blanco, G. Orabona, A. De Angeli 'Public Design of Digital Commons in Urban Places: A Case Study' (2015)81 International Journal of Human-Computer Studies 17.

[38] C. Giotitsas, A. Pazaitis, V. Kostakis 'A peer-to-peer approach to energy production' (2015) 42 Technology in Society 28.

[39] A. Matwyshyn 'The Internet of Bodies' (2019) 61 1 William & Mary Law Review 77.

[40] M. Dulong de Rosnay, F. Musiani 2021*supra* notes at 35.

[41] M. Sanfilippo, B. Frischmann, K. Standburg 'Privacy as commons: Case evaluation through the governing knowledge commons framework' (2018) 8 Journal of Information Policy 116.

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- Proposals have also been made to link privacy to labor law negotiation mechanisms and social protection, so as to develop a legal framework for the recognition of digital labor collective rights in the data employees generate. This would allow to more easily treat them as a commons.

- G. Comandé and G. Schneider[42] advocate for a dynamic interpretation of the regulatory flexibilities provided by the General Data Protection Regulation leading to 'differential' data protection regimes for research within the European data protection framework with a different impact on contractual freedom to share and aggregate personal data, which is the primary pillar of the creation of "common data spaces" under the latest European strategy for data and under the proposed Data Governance Act.

Overall, there is a worldwide recognition of the need to conceptualize innovative theoretical frameworks to govern systems based on algorithmic decision-making, and the sets of data these systems collect, produce and process in a "closed box" or "black box" approach. These theoretical frameworks can and should inform proper legal and licensing frameworks, that would best fit urban and AI data flows, and governance models based on privacy-friendly commons, decentralized and P2P infrastructure, and on post-capitalist, non-proprietary values having sharing dynamics at their core.[43]

3.2 Decentralized architectures and self-sovereign identities

Another aspect that can be worked on in order to encourage trust in digital ecosystems is the relation between choices of particular types of technical architectures and the establishment of self-sovereign identities. In Europe there have been experiments with self-sovereign identity and application of technology to re-

[42] G. Comandé, G. Schneider 'It's time. Leveraging the gdpr to shift the balance towards research-friendly EU data spaces' (2022) Common Market Law Review.

[43] G. Priora, C. Sganga 'Smart urban mobility: a positive or negative IP space? A case study to test the role of IP in fostering data-driven innovation', in M. Finck, M. Lamping, V. Moscon, H. Richter (cur), *Smart Urban Mobility. Law, Regulation and Policy* (Springer 2020).

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decentralize the web. One example is Sir Tim Berners Lee's SOLID. Another example is Ernst Hafen's data cooperation MIDATA. MIDATA contributed to the creation of an ecosystem of trust by way of giving patients the control of their own data. Drawing upon functional equivalent initiatives goes in the same direction.

These data practices are likely to be best supported by experiments with decentralized network architectures, i.e. networks that at the technical level are based on peers/equals that collaborate spontaneously and, in most cases, without requiring a central coordinating entity.[44] These networks are informed by a few core technical principles, i.e. each node of the network can act both as a supplier and as a consumer of resources, there is no central authority to which coordination is entirely delegated, and there is no entity that has a global vision (and thus a global control) of the network. This technical vision has inspired philosophers and social scientists to explore decentralized organizational forms as alternative ways not only to distribute software, files and cultural works among peers (which was the primary purposes to which peer-to-peer networks were destined in the early 2000s), but also to manage the Internet or parts of it. In a perspective of "sustainable digital development",[45] this vision can be the key to develop alternative services, applications or platforms – and at the content level, alternative knowledge or creations. Practical examples of these experimentations with decentralized architectures, which have originated in Europe, include the aforementioned SOLID Web decentralization project, or the PeerTube video platform.

Individual citizens' data stores, as proposed by Nanni et al,[46] for tracking the dynamics of COVID-19, also rely on a decentralized approach. They have been developed to collect contact and location data of persons tested positive for COVID-19. The idea behind them is to enable tracking of virus transmission chains and early detection of outbreaks in a privacy-preserving manner. The conceptual advantage of

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[44] R. Schollmeier 'A Definition of Peer-to-Peer Networking for the Classification of Peer-to-Peer architectures and applications' (2001) Proceedings of the First International Conference on Peer-to-Peer Computing 27.

[45] I. Linkov, B. D. Trump, K. Poinsatte-Jones, M. V. Florin 'Governance strategies for a sustainable digital world' (2018) 10 2 Sustainability' 440.

[46] Nanni et al (14).

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the decentralized approach lies in enabling sensitive categories of data to be shared separately and selectively - either with a back-end system or the other citizens - voluntarily and with a privacy-preserving level of granularity. It allows for detailed information gathering on infected people, it enables contact tracing, and it is also scalable to large populations.[47]

Decentralized data governance schemes strongly interrelate with self-sovereignty of the networks. The vision of self-sovereignty is highly attractive, not only for decentralized schemes, but also for big tech companies in control of data. However, noin the contexts of global (e.g. COVID-19 pandemic) or pan-European actions (e.g. UEFA EURO) individual self-sovereignty can be counter-productive, unless supported by sovereignty on a geo-political level. Europe is ideally positioned to push innovation forward because of its data quality and diversity. Prominent examples are healthcare and life sciences.

3.3 Sovereignty on a geo-political level

Sovereignty on a geo-political level can work both towards and against trust in digitization, depending on the actor's political motivation. The European legislative initiatives towards fostering data sharing and control with approaches of digitization signal willingness to protect against misuse (of technology and data) by the big technological players.

The COVID-19 pandemic has arguably fueled a crisis of sovereignty. It showed "the limits of national policy, politics and borders," according to anthropologist Arjun Appadurai.[48] By suggesting that "all national sovereigns are weak" it "knocks on the door of the Westphalian model of sovereignty in a way that Ebola, SARS, and even HIV did not." Recently, the sovereignty discourse has been mobilized in reference to the digital, acknowledging that digital infrastructure puts (national and individual)

[47] Ibid.

[48] A. Appadurai 'The COVID exception' (2020) Social Anthropology.

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sovereignty under strain.[49] Ongoing EU efforts to reclaim digital sovereignty are a case in point, such as, indeed, the plans for a Digital Services Act and a Digital Markets Act, as well as the GAIA-X project, tasked with developing EU data infrastructures to counter the dominance of global tech giants. Digital infrastructure is the "battlefield" of numerous attempts to exercise sovereignty, such as Russia's "*sovereign Internet*" and "anti-Apple" laws[50] or what has been defined as the "comeback" of the state in the governance of the internet.[51]

More work is needed to establish a systemic view on the distinct levels at which sovereignty dynamics unfold: these include citizens, government institutions and the private sector, and "hybrids" of these groups and entities as they evolve and interact with each other. The current data infrastructure, especially all the regulatory devices based on the treatment of data that have been deployed during the pandemic, alter "the social conditions under which information on the social world is produced",[52] managed and acted upon.[53] Further, this data infrastructure contributes to enact what Isin and Ruppert[54] called "sensory power" — a type of power based on "the accumulation of subject peoples" by means of sensors, involving "technologies of

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[49] See, for instance, K. Irion 'Government cloud computing and national data sovereignty' (2012) 4 3-4 Policy & Internet 40; L. Amoore, R. Raley 'Securing with algorithms: Knowledge, decision, sovereignty' (2017) 48 1 Security Dialogue 3; S. Couture, S. Toupin 'What does the notion of "sovereignty" mean when referring to the digital?' (2019) 21 10 New media & society 2305; P. Hummel, M. Braun, M. Tretter, P. Dabrock 'Data sovereignty: A review' (2021) 8 1 Big Data & Society.

[50] F. Daucé, F. Musiani 'Infrastructure-embedded control, circumvention and sovereignty in the Russian Internet: An introduction' (2021) 26 5 First Monday.

[51] B. Haggart, N. Tusikov, J. A. Scholte (eds) *Power and Authority in Internet Governance: Return of the State?* (Routledge 2021).

[52] A. Desrosières *The politics of large numbers: A history of statistical reasoning* (Harvard University Press 1998).

[53] I. Hacking 'Between Michel Foucault and Erving Goffman: between discourse in the abstract and face-to-face interaction' (2004) 33 3 Economy and society 277.

[54] E. Isin, E. Ruppert 'The birth of sensory power: How a pandemic made it visible?' (2020) 7 2 Big Data & Society.

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detecting, identifying and making people sense-able through various forms of digitized data (…) about their conduct".[55] While Europe is ideally positioned to push innovation forward in this regard, because of data quality and diversity (e.g., in healthcare and life science), it also faces unique challenges due to the particular configurations of sovereignty and data sovereignty it supports. In particular, when personal data, and especially health data - a special data category under Article 9 (1) GDPR) - are at stake, harmonization with the data protection framework is required. The task becomes even more complicated when the data critically required for pan-European actions *a priori* rests in the hands of individual entities. The matter merits attention in view of the highly fragmented and regulated data landscape in healthcare (bound by regulatory constraints, the obligations of professional secrecy, highly divergent data formats and encoding systems, languages, strict legitimation requirements, et cetera). What follows is that apart from potential benefits, the most recent developments in data analysis and infrastructure-building pose concrete challenges to (digital) sovereignty. At the same time, the above developments demonstrate various ways how citizens can keep full sovereignty on their privacy (rather in factual than in legal terms) and data.

A certain degree of synchronization established between the DGA and the GDPR lays a foundation for pan-European data research initiatives, as we consider next.

4. Interplay between the DGA and the GDPR

The DGA can become a centerpiece in the EU strategy for unleashing data sharing and fostering altruistic use of personal and non-personal data. In itself, it builds upon the established frameworks for research, in general, and on the avenues opened for research in support of public good (such as medical research) by the GDPR, in particular.[56]

[55] Ibid, 2.

[56] G. Schneider, G. Comandè 'Differentiating' (7).

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4.1 General interconnection points

By adding a clear missing infrastructural and normative link, a trustworthy setting for intermediaries should be created, allowing personal data to be used with the help of a "*personal data-sharing intermediary*". This setting should be centered on allowing data use on altruistic grounds. From a technical point of view, the DGA's nature as a proposed EU Regulation (in contrast to a Directive) permits uniform and direct application of the many elements requiring a clear common framework. Chiefly, it would introduce a uniform system and interpretation of the notification for data sharing service providers, including the mechanisms for data altruism, the basic principles that apply to the reuse of public sector data that cannot be made available as open data or are not subject to sector-specific EU legislation, and the set-up of coordination structures at the European level.

The DGA exemplifies and provides content to the so-called FAIR principles limiting the conditions for reuse "*to what is necessary to preserve the rights and interests of others in the data and the integrity of the information technology and communication systems of the public sector bodies*".[57] Such a FAIR approach is made possible precisely by the GDPR regulatory background. Indeed, the very same recital 11 echoes article 89 of the GDPR in its call for transmission (and thus reuse) of anonymous data as a default approach, while also recognizing that "provision of *anonymised or modified data"* might *"not respond to the needs of the re-user"* and, for cases of continued personal data use, suggesting alternative safeguards, such as *"on-premise or remote re-use of the data within a secure processing environment*".[58] A strikingly similar approach has already been tried within the SoBigData++ project (practiced as transnational access and/or virtual access).

In the same line of deference to the GDPR, the DGA leverages the principle of lawfulness of the processing to establish trust, reasserting that "personal data should only be transmitted for re-use to a third party where a legal basis allows such

[57] Recital 11 DGA; see also articles 5 and 11(4) DGA.

[58] Recital 11 DGA.

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transmission" ."[59] The evident preference for general interest research and data sharing of the DGA emerges in various instances. Among them is worth mentioning the possibility for public sector bodies "*to allow re-use at lower or no cost, for example for certain categories of reuses such as non-commercial re-use or scientific research purposes, or re-use by SMEs and start-ups, civil society and educational establishments, so as to incentivise such re-use in order to stimulate research and innovation*".[60]

As a possible response to criticisms that the GDPR might excessively limit reuse and personal data sharing, one may consider the notion of "*data cooperatives",* a specific category of data intermediaries including providers of data sharing services that offer their services to data subjects in the sense of Regulation (EU) 2016/679 "*to enhance individual agency and the individuals' control over the data pertaining to them.*"[61] By way of the intermediaries regulated in the DGA, data subjects would, for instance, be enabled to exercise their autonomy not only through the mechanism of wider consent[62] but also to make their personal data "manifestly public"[63] for specific purposes of general interest.[64]

4.2 Truly enabling personal data altruism

An element of data altruism introduced by the DGA is not insignificant for the dimension of trust in digital ecosystems. Indeed, data altruism is a landmark for reuse of data that needs to be encouraged and leveraged within the framework of the GDPR. It is recital 35 that states "*There is a strong potential in the use of data made available*

[59] Recital 11 DGA.

[60] Recital 20 DGA.

[61] Recital 23 DGA.

[62] Artt 6(1)(a) and 9(2)(a) GDPR.

[63] Art 9(2)(e) GDPR.

[64] G. Schneider, G. Comandè 'Differentiating' (7); G. Schneider, G. Comandè 'Differential Data Protection' (5); G. Schneider, G. Comandè 'It's time' (43).

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voluntarily by data subjects based on their consent or, where it concerns non-personal data, made available by legal persons, for purposes of general interest."[65] At the same time, it stresses that *"Support to scientific research, including for example technological development and demonstration, fundamental research, applied research and privately funded research, should be considered as well as purposes of general interest"*.[66]

The interplay between data altruism and the GDPR in the prism of fostering research is clearly highlighted in the DGA by stressing the intermediary tools it institutes and regulates: "*In accordance with Regulation (EU) 2016/679, scientific research purposes can be supported by consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research or only to certain areas of research or parts of research projects*".[67] A highly important overlap between big data science and the data protection legal framework has been achieved with regard to data (re-)processing for medical research, essentially due to the value of health as an objective of public interest.[68]

4.3 Secondary use of health data for research – a legal perspective

The comprehensive legal framework created by the GDPR and the DGA in support of science provides a strong foundation for people to trust in the digital ecosystem and an ethically-compliant research environment. A key area of overlap exists between research ethics, the science of big data mining, and legally imposed constraints under the European data protection law: the secondary use of health data for medical research. In this context, where data originally collected for one purpose (e.g. individual diagnosis or treatment), are used for another purpose (e.g. to allow a detailed comparison between the particular patient and others, to draw wider conclusions about the origins of the disease), a number of fairly stringent conditions need to be satisfied of both legal and ethical nature. Thus, both the GDPR and

[65] Recital 35 DGA.

[66] Ibid.

[67] Recital 38 DGA.

[68] Recital 53 DGA.

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normative codes of research ethics (such as the Declaration of Helsinki) often insist on the need for fresh consent from the patient to the research use. In addition, under the GDPR strict safeguards must be observed to ensure the fairness and security of the processing, including the principle of 'data minimisation', under which the data must be "*adequate, relevant, and limited to what is necessary in relation to the purposes for which they are processed*".[69]

In this regard, it appears the GDPR may contribute rather well to the building of trust relations as a key component, as mentioned earlier, to research involving the use of data, especially sensitive data of a medical kind. The patient subject retains control – the ability to veto the data processing (by refusing consent) as well as knowing that the researcher (data controller) owes an ongoing obligation to use the data in a fair and careful manner. The GDPR also equips the subject with a series of additional rights (under articles 12-20) including the right to withdraw their data from the research at any time. Under these circumstances, it is suggested that researchers working with relatively few subjects and taking the trouble to build up ties and to involve these in the overall research aim (e.g. better treatment for a given disease, from which the subject or a relative may themselves suffer) have a good chance of being able to acquire and use relevant data in an effective (as well as legally compatible) manner.

At the same time, it may be wondered how far this legal framework is favorable to larger scale research, particularly when the researcher has little (or perhaps no) direct contact with the subjects, and receives instead the data via a third-party intermediary. Here the hurdles, including the need for re-consent to different research uses and the guarantee of the subject's rights under the GDPR, may pose considerable logistical and organizational challenges. In this kind of situation, it appears that data privacy and autonomy concerns could lead to suboptimal research outcomes, though this is admittedly difficult to quantify.

A further interesting question, in the specific context of 'big data'-analytic medical research is whether the risk-based approach to data processing found in the GDPR may inhibit such research, even where, in line with normative codes of ethics, the interests and concerns of the research participants are safeguarded to the letter. This

[69] Art 5(1)(c) GDPR.

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arises in view of the need, under article 35 of the GDPR, for data processing operations "*likely to result in a high risk to the rights and freedoms of natural persons*" to be subject to a rigorous prior 'data protection impact assessment', potentially including the need for approval by the relevant supervisory authorities. Arguably, this would apply if proposed data research is likely to generate knowledge that would create a dilemma not adequately addressed by the research plan. This is certainly a risk with unsupervised data analytic processes of the kind used to make sense of large volumes of data, which discern probabilistic correlations rather than causal relations. In particular, it may lead to cases where science can predict, on the basis of a person's data, that the person has a high probability of contracting a given disease, but (lacking firm causal knowledge) not do much to stop it: here, the dilemma would be what to tell the person.

In summary, it can fairly be said that, while the GDPR contains important provisions, contributing to safe and ethical use of medical data for research, it has the potential to make both the approval and execution of such research quite complicated. While this may result in Europe lagging behind other parts of the world, where such legal restrictions do not operate, it is not clear that it will (or to what extent the legal constraints will be enforced with regard to research). For example, in the last scenario, a rule requiring data researchers to privilege data analytical processes that generate actionable causally-grounded knowledge could also provide a (scientifically) useful steer. Careful, ongoing analysis, which takes account of diverse data analytical research methods, as well as their respective strengths and weaknesses (including risks to the data subjects and wider society), will be required in order to progress towards a balanced legal and ethical solution.

5. Conclusion and steps forward

From the above discussion, it follows that the initiatives towards creating a European digital ecosystem of trust, including trustful research environments, are quite a few, spreading across regulatory, societal, technological, geo-political, and legal fields. Such initiatives encompass mechanisms integrating ethics-by-design, privacy-preserving technologies, the phenomena of data altruism, data intermediaries, self-sovereign identities and instruments for web decentralization. An important

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infrastructural and normative link has been established, thus enabling the creation of trustworthy settings facilitating safe data sharing. The avenues already opened for research, both by the FAIR principles and the legal grounds provided by the GDPR, have found due reflection and productive adoption. A remarkable sign is that such initiatives mainly pay tribute to the core values of the European society, namely fundamental rights and ethics.

The further the story goes, the more challenges emerge. In particular, it becomes evident against the background of integrating the stringent GDPR requirements into research settings, especially when health data are concerned - an important asset for individuals, healthcare and associated industries, the public and the state. The attempts to address such challenges are quite prominent, such as solutions around explainable AI, innovative data control mechanisms, and efforts to address data biases and discriminatory capacity hidden in data and algorithms. Such aspects are critical and merit ongoing reflection and an interdisciplinary approach, which goes beyond the realm of this paper but bears rich potential for further exploration.

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Comparative Law in Germany: Yesterday's Hobby or Tomorrow's Science?

André Janssen (*)

Abstract

This article focusses on the significance of comparative law for the German private law landscape in the 21st century. Is comparative law in 21st century Germany just a hobby, a game of thought, an "*intellectual adventure*" tackled by a few bored specialists, or is it perhaps more? It is maybe even tomorrow's science? In order to answer these research questions this contribution starts out with an outline of the emergence of comparative law in Germany in general, followed by an examination of its current significance in *legal education*, *legal research*, *legal practice* and in particular in *legislation* and in the *interpretation of private law by the courts*. The article comes to the conclusion that there is no "one size fits all answer" but that the value of comparative law in Germany varies depending on the field examined.

Table of contents

(*) André Janssen is Chair Professor of Civil Law and European Private Law at Radboud University, The Netherlands. This paper is partly based on a lecture I gave at Kyoto University, Japan, in 2018 and on my articles 'The Role of Comparative Law in German Private Law in the 21st Century' (in Japanese), in: T. Nakahara (eds.), *The Different Perspectives of Modern French and German Liability Law* (in Japanese) (Shôjihômu, 2020), pp. 409-440, and 'Die Bedeutung der Rechtsvergleichung für die deutsche Zivilrechtslandschaft im 21. Jahrhundert, in: A. Janssen, H. Schulte-Nölke (eds.), *Researches in European Private Law and Beyond – Contributions in Honour of Reiner Schulze's Seventieth Birthday* (Baden-Baden: Nomos, 2020), pp. 299-324.

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Keywords

Comparative law, German private law, value of comparative law in Germany, contrasting function of comparative law, control or confirmation function of comparative law, cognitive function of comparative law, comparative law interpretation as "fifth method of interpretation"

Introduction

The former member of the English House of Lords, *Lord Goff of Chieveley*, noted several years ago: "*Comparative law may have been the hobby of yesterday, but it is destined to become the science of tomorrow*".[1] If this almost prophetic sentence echoes in the ears of a German lawyer, several questions arise: Is comparative law in 21st century Germany really just a hobby, a game of thought, an "*intellectual adventure*"[2] tackled by a few bored specialists, or is it perhaps more? And if one agrees with *Lord Goff*'s basic assumption, has the importance of comparative law actually increased in the meantime, and if it has, what are the underlying reasons? And to what extent can his statement, made in 1997 with English common law in mind, (still) be applied to the German law in 2021? Let us try to shed some light on the darkness of comparative law in the German legal world.

This article, which should be understood as a little "comparative law appetizer", will focus on the significance of classical comparative law for the current German *private law* landscape.[3] Some developments at international level, beyond the comparison of

[1] R. Goff, 'The Future of Common Law' (1997) 46 *International and Comparative Law Quarterly (ICLQ)* 745, 748.

[2] B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (Tübingen: Mohr Siebeck 1983), p. 14.

[3] For the use of comparative law in German public law (especially German constitutional law) see S. Haberl, 'Comparative Reasoning in Constitutional Litigation: Functions, Methods and Selected Case Law of the German Federal Constitutional Court', in G. F. Ferrari (eds.) *Judicial Cosmopolitanism*

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national private law systems, cannot be completely ignored. This applies in particular to the internationalisation of German private law through international uniform law and comparative law-based principles, which will thus also be discussed. At this point, however, the Europeanisation of German private law through the law of the European Union and in particular through directives and regulations relevant to private law shall be set aside: on the one hand, this would go beyond the scope of this contribution, and on the other, the influence of the *acquis communautaire* on German (private) law has been extensively examined elsewhere.[4]

This contribution starts out with an outline of the emergence of comparative law in Germany (II.), in order to then examine its current significance in legal education (III.), legal research (IV.), legal practice (V.), legislation (VI.) and in the interpretation of private law by the courts (VII.). The article concludes with a short summary of the insights gained (VIII.).

1. Emergence of comparative law

The development of modern comparative law as an independent discipline, above all comparative legislative law ("*legislatorische Rechtsvergleichung*"), has its origins in the early 19th century. It was at this time that the first modern national codifications of private law in Europe were created, beginning in 1804 with the French Code Civil *("Code civil")* and in 1811 with the Austrian General Civil Code ("*Allgemeines bürgerliches Gesetzbuch*" or "*ABGB*"). Gradually, a multitude of codifications for comparative law emerged and with them the age of comparison began. This development was further accelerated by the increasing emancipation of national jurisprudence from the formerly dominant Roman law.[5]

Regarding Germany, it must also be held in mind that before 1871 there was no German state as such, only numerous individual states with their own (private law) legislation. A glance at the map of that time, displaying the various laws in place, reveals a colourful patchwork of diverging legal systems (the French Code civil, for

(Leiden: Brill, 2019) 295; S. Martini, 'Lifting the constitutional curtain? The Use of foreign precedent by the German Federal Constitutional Court', in T. Groppi, M. C. Ponthoreau (eds.), *The Use of Foreign Precedents by Constitutional Judges* (Oxford: Hart, 2013) 229.

[4] See e.g. A. Janssen, R. Schulze, 'Legal Cultures and Legal Transplants in Germany' (2011) 19 *European Review of Private Law (ERPL)* 225. On the influence of European Union Law on German law in its entirety see R. Schulze, A. Janssen, S. Kadelbach (eds.), *Europarecht: Handbuch für die deutsche Rechtspraxis* (4th edition, Baden-Baden: Nomos, 2020). For more specific information on the influence of European law on German private and commercial law see K. Langenbucher (ed.), *Europäisches Privat-und Wirtschaftsrecht* (4th edition, Baden-Baden: Nomos, 2017).

[5] Cf. in more detail A. Janssen, R. Schulze, 'Legal Cultures and Legal Transplants in Germany' (n. 4) 228.

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example, was still in force in parts of Germany until 1900), which only came to an end when the *Bürgerliches Gesetzbuch* ("*BGB*") came into force on 1 January 1900.[6] This was an additional reason why comparative law fall on such fertile ground, especially in Germany. In the last third of the 19th century, comparative law became largely institutionalised: comparative law societies and comparative law journals were founded, such as the *Zeitschrift für vergleichende Rechtswissenschaft* (1878), which still exists today.[7] The climax of the rise of comparative law was reached when the first international congress of comparative law was held in Paris in 1900, which is now known as "*the cradle of modern comparative law*".[8] With this congress at the latest, comparative law was anchored in European and German legal science and recognised as an independent discipline, even though the discussion about its actual meaning, which is still ongoing today, was only just beginning.[9]

2. Significance of comparative law in legal education

After this outline of the evolution of comparative law in Germany, let us now turn to its importance in German legal education at a university level.[10] The specific content of legal education is basically a matter for the German *Länder*. It is for them, and not the universities themselves, to conduct the final examinations in law, i.e. the first and second state law examinations ("*erstes und zweites juristisches Staatsexamen*"). Strictly speaking, therefore, there are 16 different legal studies in Germany, while the universities are also granted a certain degree of leeway. Nevertheless, it holds true for almost all universities that lectures on comparative law are offered (only) as an *optional* subject, although they are generally quite well received among students. In my personal experience, students attend these lectures primarily out of curiosity for other legal solutions and models, though they usually attend without preconceptions of what exactly comparative law involves, why it exists and how it is distinguished from other disciplines.

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[6] Cf. in more detail A. Janssen, R. Schulze, 'Legal Cultures and Legal Transplants in Germany' (n. 4) 232.

[7] The first comparative law journal was even founded as early as 1829, namely the *Kritische Zeitschrift für Gesetzgebung und Rechtssetzung des Auslandes*. However, it was discontinued in 1850.

[8] For example, I. Schwenzer, 'Development of Comparative Law in Germany, Switzerland, and Austria' in M. Reimann, R. Zimmermann (eds.), *The Oxford Handbook of Comparative Law* (Oxford: Oxford University Press, 2006) 77.

[9] See I. Schwenzer, 'Development of Comparative Law in Germany, Switzerland, and Austria' (n. 8) 70, on the then following development of comparative law in Germany (and in Austria and Switzerland) in the 20th century.

[10] Cf. in more detail see B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 15.

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In terms of content, the lectures are regularly limited to comparative *private* law. The history, objectives and methodology of comparative law (e.g. "*Makro- und Mikrovergleichung*", "*funktionale Rechtsvergleichung*") are taught, followed by the doctrine of legal systems ("*Rechtskreislehre*", here the European legal systems and the USA clearly take priority)[11] and certain selective comparisons taken from the fields of contract and tort law. To a lesser extent, unjust enrichment and property law are also given some consideration. Within the selective comparisons, questions concerning "specific performance", the meaning of "good faith" or the necessity of "consideration" in common law and civil law are classic items on the agenda. In the other subjects of legal education, comparative law usually receives little or no attention. There is generally no mention of it in the traditional lectures on the BGB, the desirable link to comparative law is regularly not established.[12] Comparative law does not form part of the two state law examinations, although the university grade is sometimes included in the final results of the first state examination.

Both the possibility of spending a semester abroad in another European country within the framework of the Erasmus programme and the acquisition of an LL.M. degree in a mostly English-speaking country are very popular among German law students. They contribute at least to dealing with foreign legal concepts and improving language skills. Admittedly, this does not replace a genuine comparative law education and we need to see what impact COVID-19 is going to have here.

All in all, the importance of comparative law in legal education can be considered rather low, as it is not a compulsory subject and is often irrelevant in lectures on other subjects.[13] Both of these observations are regrettable, especially since, in my experience, there exist a fundamental curiosity among students in comparative law. The minor role that comparative law takes on is in part a consequence of the political intent of seeing students through their studies as quickly as possible and making them available to the job market rather sooner than later. With legal education following these goals, comparative law appears to many more as a redundant exercise than a genuine enrichment.

3. Significance of comparative law in legal research

[11] The doctrine of legal systems is clearly recognisble in K. Zweigert, H. Kötz, *Einführung in die Rechtsvergleichung* (3rd edition, Tübingen: Mohr Siebeck, 1996) 62.

[12] Merely the influence of certain EU directives implemented in the BGB is addressed in private law lectures.

[13] Interesting on the internationalization of German legal education M. Stürner, 'How International Should the German Einheitsjurist be?' in C. Jamin, W. van Caenegem (eds.), *The Internationalisation of Legal Education* (Vienna: Springer, 2016)) 115.

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It is undisputed that Germany has a long tradition of comparative law research.[14] The *Max-Planck-Institut für ausländisches und internationales Recht* in Hamburg is world-renowned as a comparative law institution and welcomes many foreign guests every year.[15] There is hardly a German university that does not have at least one chair of comparative law, although these chairs almost always include other areas such as private law, European private law or private international law. But regardless of the exact designation of the chair, many German colleagues, by their own initiative, work on and with comparative law. A strict separation between private law researchers and comparative law researchers and their research, as is e.g. known in Italy between "*civilisti*" and "*comparatisti*", is unknown in Germany.

Some of the most important publications worldwide in the field of comparative law have been written in German or at least by Germans, most notably "*Einführung in die Rechtsvergleichung*" by *Konrad Zweigert* and *Hein Kötz,* which has been translated into many languages.[16] This work, although unfortunately no longer updated (the last edition dates back to 1996), is regularly consulted even by the German legislator and exemplifies the connection between legal research and legislation, which is important in Germany and seems to be less pronounced in many other countries. More recent examples are found in the impressive work (comprising more than 1000 pages) by *Uwe Kischel* entitled "*Rechtsvergleichung*",[17] the somewhat more compact (500 pages) "*Comparative Law*" by *Mathias Siems*[18] and the short textbook "*Rechtsvergleichung*" by *Karl August Prinz von Sachen Gessaphe.*[19] The works of *Thomas Kadner Graziano,* including "*Comparative Contract Law - Cases, Materials and Exercises*",[20] "*Europäisches Vertragsrecht – Übungen zur Rechtsvergleichung und Harmonisierung des Rechts*"[21] and "*Comparative Tort Law – Cases, Materials and Exercises*",[22] are thematically narrower, but nevertheless very much worth reading.

Many doctoral students take a comparative law approach, meaning that the number of comparative law doctoral theses is quite high, although there are clear distinctions

[14] See also B. Markesinis, J. Fedtke, *Engaging with Foreign Law* (Oxford: Hart, 2009) 185.
[15] See https://www.mpipriv.de/de/pub/aktuelles.cfm for more details.
[16] K. Zweigert, H. Kötz, *Einführung in die Rechtsvergleichung* (n. 11).
[17] U. Kischel, *Rechtsvergleichung* (Munich: Beck, 2015).
[18] M. Siems, *Comparative Law* (2nd edition, Cambridge: Cambridge University Press, 2018).
[19] K. A. Prinz zu Sachen Gessaphe, *Rechtsvergleichung* (Munich: Beck, 2011). The book *Macht und Ohnmacht der Rechtsvergleichung* by Großfeld, which has already been quoted here (see n. 2), is also worth reading, although it does not deal systematically with comparative law.
[20] T. Kadner-Graziano, *Comparative Contract Law - Cases, Materials and Exercises* (2nd edition, Cheltenham: Edward Elgar, 2019).
[21] T. Kadner-Graziano, *Europäisches Vertragsrecht - Übungen zur Rechtsvergleichung und Harmonisierung des Rechts* (Baden-Baden: Nomos, 2008).
[22] T. Kadner-Graziano, *Comparative Tort Law – Cases, Materials and Exercises* (Abingdon: Routledge, 2018).

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in quality. Several leading comparative law journals, but especially the *Rabel Zeitschrift für ausländisches und internationales Privatrecht,* founded in 1927, and the even older *Zeitschrift für vergleichende Rechtswissenschaften* mentioned above, originate from Germany and enjoy great popularity at home and abroad. A publication in the first-mentioned journal still carries particular weight in German academia. The *Zeitschrift für Europäisches Privatrecht*, although not a comparative law journal in the strict sense, also frequently publishes high-quality comparative law articles and enjoys an excellent reputation in the academic world.

Traditionally, the focus in Germany has been on comparative *private* law, applying the functional method of comparative law.[23] The comparison of criminal law or public law is not unknown, but falls behind comparative private law in importance. The national legal systems continue to be the main points of reference for comparative private law. For a long time, this interest was very clearly focused on European legal systems and the USA. In the meantime, however, the increased importance of Islamic law and, even more so, of Asian legal systems has become apparent and is increasingly reflected in comparative law in Germany academia.[24] Chinese and Japanese private law are particularly noteworthy in this respect; both legal systems have even become the subject of independent German journals.[25]

In addition to the classic comparison of national legal systems, a further development within comparative private law is emerging as a result of the continuing Europeanisation and internationalisation of law, namely the increasing analysis of international uniform law (above all with the *United Nations Convention on Contracts for the International Sale of Goods* or also known as the "*CISG*"), model laws and principles or legislative drafts based on comparative law. With regard to the latter, the *Principles of European Contract Law ("PECL")*,[26] the *Principles of European Tort Law ("PETL")*,[27] the *Unidroit Principles of International Commercial Contracts ("PICC")*,[28] the draft for a *Common European Sales Law ("CESL")*[29] and the *Draft Common Frame of Reference ("DCFR")*[30] should be mentioned in particular.

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[23] See U. Kischel, *Rechtsvergleichung* (n. 17) 93. on the concept of the functional comparative method.
[24] See for example U. Kischel, *Rechtsvergleichung* (n. 17) 729 (for Asian law), 856 (for Islamic law).
[25] See the *Zeitschrift für Chinesisches Recht* and the *Zeitschrift für Japanisches Recht*.
[26] For the PECL see O. Lando, H. Beale (eds.), *Principles of European Contract Law, Part I and II*, (Alphen aan den Rijn: Kluwer, 2000); O. Lando, E. Clive, A. Prüm, R. Zimmermann (eds.), *Principles of European Contract Law, Part III* (Alphen aan den Rijn: Kluwer, 2003).
[27] For the PETL see European Group on Tort Law (ed.), *Principles of European Tort Law: Text and Commentary* (Vienna: Springer, 2005).
[28] For the PICC see S. Vogenauer (ed.), *Commentary on the UNIDROIT Principles of International Commercial Contracts (PICC)* (2nd edition, Oxford: Oxford University Press, 2015).
[29] For the CESL see R. Schulze (ed.), *Common European Sales Law* (Munich: Beck, 2012).
[30] For the DCFR see C. von Bar, E. Clive, H. Schulte-Nölke (eds.), *Principles, Definitions and Model Rules of European Private Law: Draft Common Frame of Reference (DCFR) - Outline Edition* (Munich: Beck, 2009).

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Methodologically, there have been some interesting developments in German academia with regard to comparative law in recent times. For example, research on the European Union's acquis communautaire has largely developed into an independent branch of research within comparative law. Based on this approach, *Acquis Principles* have been published by the *Aquis-Group.*[31] The idea of legal transplants, which originates in the Anglo-American legal field, has also gained in importance within German comparative law research, although it remains to be seen to what extent it will emerge as an independent approach within comparative law.[32]

4. Significance of comparative law in legal practice

Comparative law can play an important role in German legal practice in at least two distinctive situations. First, comparative law is of use if, due to the applicable private international law, the possibility of applying at least two different legal systems arises. Here, it is part of the lawyer's duty towards his client to compare the possible applicable legal systems with each other and, the concept of forum shopping in mind, to decide on the legal system promising the best result for the client. Second, comparative legal considerations in legal practice may also prove useful where German law is applicable that has clearly been influenced by foreign legal concepts (within the framework of the so-called historic interpretation of a national provision) or in the event (which will be substantiated below) that the German courts are generally open to comparative legal considerations and attach enhanced importance to them.

However, it can certainly be said that comparative law arguments produced by legal practitioners are the very rare exception in legal practice – be it due to a lack of time or a lack knowledge of foreign legal systems. For German legal practitioners, comparative law is therefore, if at all, an intellectual hobby and not very conducive to the exercise of their profession, perhaps even a hindrance in that it is difficult to communicate to clients. It is only when the interpretation of international uniform law[33] or of "Europeanised" national law is on the agenda that legal practitioners are

[31] H. Schulte-Nölke, 'European Research Group on Existing Community Private Law ("Acquis Group") established' (2002) 10 *Zeitschrift für Europäisches Privatrecht (ZEuP)* 893; R. Schulze, 'Die Acquis-Grundregeln und der gemeinsamen Referenzrahmen' (2007) 15 *Zeitschrift für Europäisches Privatrecht (ZEuP)* 731.

[32] The "father" of legal transplants is *Alan Watson*. See for example his works *Legal Origins and Legal Change* (London: The Hambledon Press, 1991) and *Legal Transplants: An Approach to Comparative Law* (2nd edition, Athens/London: The University of Georgia Press, 1993); see also A. Janssen, R. Schulze, 'Legal Cultures and Legal Transplants in Germany' (n. 4) 225; M. Siems, *Comparative Law* (n. 18) 231.

[33] The same applies at least in part to private international law. Cf. B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 55.

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regularly forced to deal with foreign sources and judgments and use them to support their own position.[34]

Beyond the forms of application of comparative law in legal practice, it may also be interesting for the foreign reader to understand how the German culture of legal practice is changing in times of globalisation.[35] Hence, a few brief remark on this topic: At least among the large law firms based in Germany, English is gaining increasing acceptance not only as the language of negotiations but also as the language contracts are drafted in, even if the agreed place of litigation or arbitration is located in Germany and German law is to be applied.[36] The choice of English as the language of the contract has far-reaching consequences, as it not only makes the Anglo-American terminology available, but also, consciously or unconsciously, the underlying concepts (such as the use of "breach of warranty" or "breach of condition").[37]

In addition, in certain, particularly globalised areas of law, German terms for English expressions are difficult to determine or are generally on the decline. This is true, for example, in the field of mergers and acquisitions, where the German word "*Unternehmenskauf*" is rarely used anymore.[38] Often, the German legal terminology does not provide any equivalents to Anglo-American terms at all (such as "due diligence", "leasing", "franchising" or "e-commerce"), so that only the English term together with the underlying concept can be adopted.

Under the impression of Anglo-American law, however, not only terms and legal concepts are adopted, but German contract drafting practice itself is also changing. Contracts from the common law world are mostly worded more precisely, but are also much longer and, from a German point of view, more confusing than the traditional German form of contract drafting.[39] However, due to the increasing

[34] The mere use of foreign sources and judgments in these cases is of course not comparative law in the strict sense.

[35] See in general A. Janssen, R. Schulze, 'Legal Cultures and Legal Transplants in Germany' (n. 4) 225.

[36] Cf. in more detail G. *Maier-Reimer*, 'Englische Vertragssprache bei Geltung deutschen Rechts' (2010) 60 *Anwaltsblatt (AnwBl)* 13.

[37] Cf. in more detail K.-P. *Berger*, 'Die Anglisierung des Wirtschaftsrechts', in B. Grunewald/H. P. Westermann (eds.), *Festschrift für Georg Maier-Reimer zum 70. Geburtstag* (Munich: Beck, 2010) 17.

[38] See on this topic M. Hentzen, 'Hegemonie oder Symbiose: Zur Rezeption des US-amerikanischen Rechts in der Vertragspraxis des M&A-Geschäfts', in W. Ebke, S. Elsing, B. Großfeld, G. Kühne (eds.), *Das deutsche Wirtschaftsrecht unter dem Einfluss des US-amerikanischen Rechts* (Frankfurt: Verlag Recht und Wirtschaft, 2011) 101; V. Treibel, 'Anglo-amerikanischer Einfluss auf Unternehmenskaufverträge in Deutschland - eine Gefahr für die Rechtsklarheit?' (1998) 43 *Recht der Internationalen Wirtschaft (RIW)* 1.

[39] For the underlying reasons see P. Mankowski, 'Rechtskultur - Eine rechtsvergleiche-anekdotische Annäherung an einem schwierigen und vielgesichtigen Begriff' (2009) 64 *Juristenzeitung (JZ)* 329; V. Treibel (n. 38) 4.

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Americanisation, there is a recognisable tendency in Germany to formulate contractual texts in ever greater detail, at least for international matters.[40]

5. Significance of comparative law in legislation

Let us now turn to the significance of comparative law for German legislation in the field of private law.[41] There is no doubt that the German legislator regularly makes use of comparative law in major private law legislative projects. However, he uses comparative law to different ends: Sometimes a *contrasting function* ("*Kontrastfunktion*") is used, i.e. the legislator points to foreign models in order to reject them and take a different path for Germany. This often applies to certain elements of the US legal system that are considered incompatible with German legal culture. One example is found in the retention of the requirement of fault ("*Verschulden*") for contractual liability. During the reform of the law of obligations ("*Schuldrechtsreform*") in 2002 the legislator pointed to the common law strict liability-approach, just to then advocate the preservation of the requirement of fault.[42]

Even if there is no supporting statistical data, it seems likely that the *control or confirmation function* ("*Kontroll- oder Bestätigungsfunktion*") is used more often. The legislator then refers to identical or similar solutions within other legal systems in support of his own position, in order to emphasise the element of decisional harmony. Almost never, or at least very rarely, does the legislator, when creating new law, rely exclusively on another legal system in the sense of a genuine and sole *cognitive function* ("*Erkenntnisfunktion*").

Such a separation of functions, although it may seem useful in theory, is of course not always feasible in practice because the motives and weighting of the legislator's comparative law considerations are not always precisely discernible. This is why it is sometimes difficult to determine the exact value of comparative law when deciding on a solution model.

The fact that the German legislator relies on comparative law has practical reasons as well. These reasons can be found in the following maxim expressed by the famous *Rudolph Ihering:*

> "*The question of the reception of foreign legal institutions is not a question of nationality, but a simple question of expediency, of need. No one will fetch from afar*

[40] For more details on this subject see M. *Hentzen* (n. 38) 108.

[41] See also U. Drobnig, P. Dopffel, 'Die Nutzung der Rechtsvergleichung durch den deutschen Gesetzgeber' (1982) 46 *Rabel Zeitung für ausländisches und internationales Privatrecht (RabelsZ)* 253; B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 38; B. Markesinis, J. Fedtke (n. 14) 177.

[42] Bundestag-Drucksache 14/6040, 131.

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> *what he can find at home just as well or better, but only a fool will reject the cinchona bark for the reason that it has not grown on his cabbage patch"* [43]

The legislator can therefore save time and resources in the preparation of legal texts if he uses existing solutions.[44] Furthermore, the experience that has been gained abroad in the context of the adopted foreign solution represents an important practical source of information, which is all the more important the more the other country is economically and culturally comparable with Germany. The legislator is relieved of the necessity of testing the practical effectiveness of the new law through the use of a foreign "laboratory", at least if the parameters of the two countries are comparable.

Concerning the reference points used by the legislator (which are taken mostly from German comparative law publications), a clear change has taken place.[45] For earlier legislative projects, reference was made almost exclusively to the law of foreign legal systems, and the closer Germany was legally, economically and socially comparable with the other state, the more intensively so. This means that the legislator has particularly drawn on the law of other European legal systems (and here above all Switzerland and Austria), and somewhat less dominant the USA, and continues to do so intensively. Comparative legal considerations with other national legal systems (e.g. from Africa, Asia or South America) were and are still rare, but not completely unheard-of.

In the last two decades, however, the German legislator has also made increasing use of two other sources of law in the field of private law, namely international uniform law (here above all the CISG) and principles developed on the basis of comparative law, in particular the PECL and the PICC. The influence of foreign legal systems (1.), of international uniform law (2.) and of soft law instruments (3.) on German legislation will be discussed below by way of example.

5.1. Foreign legal systems

If one looks at the beginnings of Germany as a state, it becomes apparent that the German legislator has always made use of comparative law with reference to foreign

[43] R. Ihering, *Geist des römischen Rechts auf den verschiedenen Stufen seiner Entwicklung* 3, 1 (Leipzig: Breitkopf und Härtel, 1865) 8. The German original reads as follows: "*Die Frage von der Rezeption fremder Rechtseinrichtungen ist nicht eine Frage der Nationalität, sondern eine einfache Frage der Zweckmäßigkeit, des Bedürfnisses. Niemand wird von der Ferne holen, was er daheim ebenso gut oder besser hat, aber nur ein Narr wird die Chinarinde aus dem Grund zurückweisen, weil sie nicht auf seinem Krautacker gewachsen ist.*"

[44] This is an important reason for the reception of foreign law, especially in smaller countries.

[45] For the referenced sources used see B. Markesinis, J. Fedtke (n. 14) 178.

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legal systems. Even the General German Exchange Code ("*Allgemeine Deutsche Wechselordnung*") of 1848 and the General German Commercial Code ("*Allgemeines Deutsche Handelsgesetzbuch*") of 1861, which were the first uniform laws in the field of private law due to their implementation in all German states of the German Federation, are based on comparative law considerations. The same applies to the Bankruptcy Code ("*Konkursordnung*") of 1877, as is clear from the explanatory memorandum to the draft.[46] And even when the BGB of 1900 was created, reference was repeatedly made to numerous foreign legal systems (including France, Switzerland or Austria).[47]

Traditional comparative law has retained its importance for current German legislation. It is possible to identify at least three situations, although not always clearly distinguishable from one another, in which the legislator continues to resort to other legal systems. Intensive comparative law considerations are often conducted to solve new legal questions which arise due to technical or social changes. An example of this is the earlier creation of registered civil partnerships ("*eingetragende Lebenspartnerschaften*") for homosexual couples. At the time, the Ministry of Justice had commissioned a detailed study with a scientific institution that served to prepare the drafting of the provisions in German family law within this area.[48] The experience that other states had gained with their legislation then formed one of the bases for the decision of the German legislator to introduce registered civil partnerships.[49] In the meantime, however, the Civil Partnership Act ("*Lebenspartnerschaftsgesetz*") has been rendered redundant due to the admission of same-sex marriage by the Act on the Introduction of the Right to Marry for Persons of the Same Sex ("*Gesetz zur Einführung des Rechts auf Eheschließung für Personen gleichen Geschlechts*") of 2017.[50] However, comparative legal references to numerous legal systems can also be found in the materials for this Act. To name just one example:

> "*Finally, the legal systems of other countries offer further evidence that the concept of the gender difference of the spouses is outdated. Recently, the Republic of Ireland has opened up marriage to same-sex couples. Civil marriage for persons of the same sex has been introduced in Belgium, the Netherlands, France, Luxembourg, Finland, Canada, South Africa, Spain, Norway, Sweden, Portugal, Iceland, Denmark,*

[46] B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 41.
[47] B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 43 particularly emphasises the influence of the Swiss Code of Obligations of 1881, which in turn is based on comparative law studies.
[48] Cf. the comprehensive expert opinions in J. Basedow, K. J. Hopt, H. Kötz, P. Dopffel (eds.), *Die Rechtsstellung gleichgeschlechtlicher Lebensgemeinschaften* (Tübingen: Mohr Siebeck, 2000).
[49] See in this respect the comparative legal considerations in the draft Law Supplementing the Civil Partnership Act and Other Laws in the Area of Adoption Law, Bundestag-Drucksache 17/1429, 3.
[50] Bundesgesetzblatt I 2017, 2787.

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> *Argentina, Brazil, Uruguay, New Zealand, as well as in Scotland, England and Wales, in 41 states of the USA and the District of Columbia, as well as in two states and in the capital of Mexico. In addition, same-sex marriages are recognised in Israel."* [51]

In addition, the legislator falls back on foreign experience in static legal questions, i.e. questions that are relatively independent of technical and social innovations, when it comes to fundamental and yet unsatisfactorily solved classical problems of private law.[52] Examples of this are the reform of the law of obligations and the reform of the law of damages ("*Schadensersatzrechtsreform*") of 2002, which have both significantly redesigned the BGB.[53] For instance, when reforming the law of damages with regard to the introduction of immaterial damages in the case of contractual liability and strict liability,[54] the legislator referred to the legal situation in several other European countries and then codified in § 253 BGB[55] a highly controversial dispute in German tort law which is more than a hundred years old.[56] The reform of the law of obligations, the actual occasion for which was mainly the implementation of the Consumer Sales Directive 1999/44/EC, represents the largest reform of German private law ever. For this reform, the German legislator used not only the CISG, the PECL and the PICC but also numerous foreign legal systems.[57] This applies, for example, to the culpa in contrahendo, i.e. the pre-contractual liability ("*Verschulden bei Vertragsschluss*"), which was previously not codified and is now enshrined in § 311 BGB.[58] The legislator relied on French, Swiss, Italian and US American law to this

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[51] Bundesrat-Drucksache 273/15, 5, followed by further comparative legal considerations. The original German version reads as follows: "*Schließlich bieten die Rechtsordnungen anderer Länder weitere Anhaltspunkte dafür, dass das Konzept der Geschlechtsverschiedenheit der Ehegatten überholt ist. Jüngst hat die Republik Irland die Ehe für gleichgeschlechtliche Paare geöffnet. In den Ländern Belgien, Niederlande, Frankreich, Luxemburg, Finnland, Kanada, Südafrika, Spanien, Norwegen, Schweden, Portugal, Island, Dänemark, Argentinien, Brasilien, Uruguay, Neuseeland sowie in Schottland, England und Wales, in 41 Bundesstaaten der USA und dem District of Columbia, sowie in zwei Bundesstaaten und in der Hauptstadt Mexikos wurde die Zivilehe für Personen gleichen Geschlechts eingeführt. Darüber hinaus werden gleichgeschlechtliche Ehen in Israel anerkannt.*"

[52] It is precisely for this group of cases, however, that the legislator is increasingly resorting to international uniform law and principles, as will be explained in more detail below.

[53] See Bundestag-Drucksache 14/6040 and Bundestag-Drucksache 14/7752.

[54] Previously, compensation for immaterial damages under § 847 BGB old version was only possible in tort law and only in the case of culpable conduct.

[55] § 253 BGB reads: "*(1) Money may be demanded in compensation for any damage that is not pecuniary loss only in the cases stipulated by law. (2) If damages are to be paid for an injury to body, health, freedom or sexual self-determination, reasonable compensation in money may also be demanded for any damage that is not pecuniary loss.*"

[56] Bundestag-Drucksache 14/6040, 15.

[57] Soon more on the influence of the CISG, the PECL and the PICC on German law.

[58] § 311 BGB reads: "*(1) In order to create an obligation by legal transaction and to alter the contents of an obligation, a contract between the parties is necessary, unless otherwise provided by statute. (2) An obligation with duties under section 241(2) also comes into existence by 1. the commencement of contract negotiations, 2. the initiation of a contract where one party, with regard to a potential contractual relationship, gives the other party the possibility of*

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end.[59] With regard to the codification of the doctrine of change of circumstances ("*Wegfall der Geschäftsgrundlage*") in the current § 313 BGB,[60] the legislator referred to the legal situation in England, France, Italy, Greece, the Netherlands, Switzerland, the USA and even the German Democratic Republic.[61] When introducing § 314 BGB,[62] which deals with continuing obligations ("*Dauerschuldverhältnissen*"), in addition to art.

affecting his rights, legal interests and other interests, or entrusts these to him, or 3. similar business contacts. (3) An obligation with duties under section 241(2) may also come into existence in relation to persons who are not themselves intended to be parties to the contract. Such an obligation comes into existence in particular if the third party, by laying claim to being given a particularly high degree of trust, substantially influences the pre-contract negotiations or the entering into of the contract."

[59] Bundestag-Drucksache 14/6040, 161.

[60] § 313 BGB reads: "*(1) If circumstances which became the basis of a contract have significantly changed since the contract was entered into and if the parties would not have entered into the contract or would have entered into it with different contents if they had foreseen this change, adaptation of the contract may be demanded to the extent that, taking account of all the circumstances of the specific case, in particular the contractual or statutory distribution of risk, one of the parties cannot reasonably be expected to uphold the contract without alteration. (2) It is equivalent to a change of circumstances if material conceptions that have become the basis of the contract are found to be incorrect. (3) If adaptation of the contract is not possible or one party cannot reasonably be expected to accept it, the disadvantaged party may revoke the contract. In the case of continuing obligations, the right to terminate takes the place of the right to revoke."*

[61] Bundestag-Drucksache 14/6040, 174ff. Incidentally, it is noticeable that the German legislator seems to have relatively little direct recourse to foreign literature or foreign law in general. Rather, the classical comparative law works such as Zweigert/Kötz, 'Einführung in die Rechtsvergleichung' (see, for example, with regard to the reform of the law of obligations, Bundestag-Drucksache 14/6040, 131, 175) or C. von Bar, *Gemeineuropäisches Deliktsrecht*, 1 (Munich: Beck, 1996) and 2 (Munich: Beck, 1999) are usually consulted and quoted (see, for example, with regard to the reform of the law of damages, Bundestag-Drucksache 14/7752, 15, 17, 31). In some cases, however, considerations of foreign law are also made without any indication of the source (see, for example, Bundestag-Drucksache 14/6040, 177).

[62] § 314 BGB reads: "*(1) Each party may terminate a contract for the performance of a continuing obligation for a compelling reason without a notice period. There is a compelling reason if the terminating party, taking into account all the circumstances of the specific case and weighing the interests of both parties, cannot reasonably be expected to continue the contractual relationship until the agreed end or until the expiry of a notice period. (2) If the compelling reason consists in the breach of a duty under the contract, the contract may be terminated only after the expiry without result of a period specified for relief or after a warning notice without result. Section 323 (2) number 1 und 2 applies, with the necessary modifications, as regards the dispensability of specifying a period for such relief and as regards the dispensability of a warning notice. Specifying a period for relief and issuing a warning notice can also be dispensed with if special circumstances are given which, when the interests of both parties are weighed, justify immediate termination. (3) The person entitled may give notice only within a reasonable period after obtaining knowledge of the reason for termination. (4) The right to demand damages is not excluded by the termination.*"

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73 CISG,[63] reference was made especially to arts. 1559-1570 of the Italian Civil Code ("*codice civile*"), which were then even used as a model.[64]
Finally, comparative law is used by the legislator rather incidentally and sometimes even without disclosure to solve certain, factually limited individual problems. As an example, § 661a BGB,[65] introduced in 2000, can be cited, with which the legislator wanted to counteract the inadmissible practice of businesses sending consumers notifications of alleged winnings, but never paying out these winnings. When this provision was created, the Austrian regulation, more precisely § 5j of the now defunct Austrian Consumer Protection Act ("*Konsumentenschutzgesetz*"), was adopted almost verbatim, without however mentioning this adoption in the legislative materials. Such covert comparative law is regrettable, since the adoption of the Austrian provision is obvious and undisputed both in the legal literature and at the Federal Court of Justice ("*Bundesgerichtshof*").[66] The legislator is called upon to disclose his comparative law considerations, especially with view to a subsequent historical interpretation by the courts.

5.2. International uniform law

The German legislator makes use not only of foreign legal systems but also, as mentioned above, increasingly relies on international uniform law, mainly for the solution of fundamental and so far unsatisfactorily regulated classical problems of private law. An example of this development is the influence of the CISG, which despite its weaknesses is considered a successful mixture of common law and civil law, on the German Civil Code.[67] In reforming the law of obligations, the legislature has drawn considerable inspiration from the CISG and reformed the German law of

[63] Art. 73 CISG reads: "*(1) In the case of a contract for delivery of goods by instalments, if the failure of one party to perform any of his obligations in respect of any instalment constitutes a fundamental breach of contract with respect to that instalment, the other party may declare the contract avoided with respect to that instalment. (2) If one party's failure to perform any of his obligations in respect of any instalment gives the other party good grounds to conclude that a fundamental breach of contract will occur with respect to future instalments, he may declare the contract avoided for the future, provided that he does so within a reasonable time. (3) A buyer who declares the contract avoided in respect of any delivery may, at the same time, declare it avoided in respect of deliveries already made or of future deliveries if, by reason of their interdependence, those deliveries could not be used for the purpose contemplated by the parties at the time of the conclusion of the contract.*"
[64] Bundestag-Drucksache 14/6040, 177.
[65] § 661a BGB reads: "*An entrepreneur who sends promises of prizes or comparable announcements to consumers and creates the impression through the design of such mailings that the consumer has won a prize must give the consumer that prize."*
[66] Bundesgerichtshof, Entscheidungen des Bundesgerichtshofs in Zivilsachen (BGHZ) 153, 82, 90.
[67] See on the question of the CISG as a successful legal "melange" between common law and civil law A. Janssen, N. Ahuja, 'Legal Laboratory CISG: A Successful Hybrid between Common Law and Civil Law?' (2017) 21 *Vindobona Journal of International Commercial Law and Arbitration (VJICLA)* 129.

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obligations on the basis of some of the fundamental decisions of the Convention.[68] The CISG has left clear traces in the German law of obligations, for example in the remedy system, in the concept of breach of duty ("*Pflichtverletzung*") according to § 280 BGB,[69] the introduction of the anticipatory breach according to § 323(4) BGB,[70] and in the determination of the defects as to quality ("*Sachmangel*") according to § 434 BGB.[71] In part, however, the influence of the CISG on today's BGB is not immediately visible since many elements of the Convention were already taken up by the Consumer Sales Directive 1999/44/EC. Implementing the directive did not necessitate an explicit reference to the CISG itself. Thus, for example, art. 35 CISG[72] was the inspiration for the creation of art. 2 of the Directive,[73] which was subsequently

[68] As already mentioned, art. 73 CISG was one of the guiding principles in the creation of § 314 BGB, which deals with continuing obligations.

[69] § 280 BGB reads: "*(1) If the obligor breaches a duty arising from the obligation, the obligee may demand damages for the damage caused thereby. This does not apply if the obligor is not responsible for the breach of duty. (2) Damages for delay in performance may be demanded by the obligee only subject to the additional requirement of section 286. (3) Damages in lieu of performance may be demanded by the obligee only subject to the additional requirements of sections 281, 282 or 283.*"

[70] § 323(4) BGB reads: "*The obligee may revoke the contract before performance is due if it is obvious that the requirements for revocation will be met.*"

[71] § 434 BGB (in the version before the implementation of the Directive (EU) 2019/771 on Certain Aspects Concerning Contracts for the Sale of Goods) reads: "*(1) The thing is free from material defects if, upon the passing of the risk, the thing has the agreed quality. To the extent that the quality has not been agreed, the thing is free of material defects 1. if it is suitable for the use intended under the contract, 2. if it is suitable for the customary use and its quality is usual in things of the same kind and the buyer may expect this quality in view of the type of the thing. Quality under sentence 2 no. 2 above includes characteristics which the buyer can expect from the public statements on specific characteristics of the thing that are made by the seller, the producer (section 4 (1) and (2) of the Product Liability Act [Produkthaftungsgesetz]) or his assistant, including without limitation in advertising or in identification, unless the seller was not aware of the statement and also had no duty to be aware of it, or at the time when the contract was entered into it had been corrected in a manner of equal value, or it did not influence the decision to purchase the thing. (2) It is also a material defect if the agreed assembly by the seller or persons whom he used to perform his obligation has been carried out improperly. In addition, there is a material defect in a thing intended for assembly if the assembly instructions are defective, unless the thing has been assembled without any error. (3) Supply by the seller of a different thing or of a lesser amount of the thing is equivalent to a material defect.*"

[72] Art. 35 CISG reads: "*(1) The seller must deliver goods which are of the quantity, quality and description required by the contract and which are contained or packaged in the manner required by the contract. (2) Except where the parties have agreed otherwise, the goods do not conform with the contract unless they: (a) are fit for the purposes for which goods of the same description would ordinarily be used; (b) are fit for any particular purpose expressly or impliedly made known to the seller at the time of the conclusion of the contract, except where the circumstances show that the buyer did not rely, or that it was unreasonable for him to rely, on the seller's skill and judgment; (c) possess the qualities of goods which the seller has held out to the buyer as a sample or model; (d) are contained or packaged in the manner usual for such goods or, where there is no such manner, in a manner adequate to preserve and protect the goods. (3) The seller is not liable under subparagraphs (a) to (d) of the preceding paragraph for any lack of conformity of the goods if at the time of the conclusion of the contract the buyer knew or could not have been unaware of such lack of conformity.*"

[73] Art. 2(1-2) Consumer Sales Directive 1999/44/EC reads: "*(1) The seller must deliver goods to the consumer which are in conformity with the contract of sale. (2) Consumer goods are presumed to be in conformity with the contract if they: (a) comply with the description given by the seller and possess the qualities of the goods which the seller has held out to the consumer as a sample or model; (b) are fit for any particular purpose for which the consumer requires them and which he made known to the seller at the time of conclusion of the contract and which the seller has accepted; (c) are*

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transposed into § 434 BGB. The system of legal remedies laid down in arts. 45ff. CISG served as the model for art. 3 of the Directive,[74] which played an important role in restructuring the legal remedy system in German Law in 2002. In these instances, the CISG influences the German Code via EU law. This development will continue with Directive (EU) 2019/771 on Certain Aspects Concerning Contracts for the Sale of Goods, which is to be implemented by 1 January 2022 and which will repeal the Consumer Sales Directive 1999/44/EC. This new Directive also incorporates numerous elements taken from the CISG. The same applies to the accompanying Directive (EU) 2019/770 on Certain Aspects Concerning Contracts for the Supply of Digital Content and Digital Services.

5.3. Soft law instruments

Similarly, the influence of soft law instruments, understood here as non-binding sets of rules drawn up by scholars on the basis of comparative law, on German legislation has increased considerably over the last two decades. As already briefly mentioned, both the PECL[75] and the PICC[76] have been intensively used for the reform of the law of obligations, although the solutions found there, unlike in other legal systems and the CISG, are not, or at least only very rarely, applied in practice. In addressing the question of impossibility, both these sets of rules were mentioned and examined in

fit for the purposes for which goods of the same type are normally used; (d) show the quality and performance which are normal in goods of the same type and which the consumer can reasonably expect, given the nature of the goods and taking into account any public statements on the specific characteristics of the goods made about them by the seller, the producer or his representative, particularly in advertising or on labelling."

[74] Art. 3 Consumer Sales Directive 1999/44/EC reads: "*(1) The seller shall be liable to the consumer for any lack of conformity which exists at the time the goods were delivered. (2) In the case of a lack of conformity, the consumer shall be entitled to have the goods brought into conformity free of charge by repair or replacement, in accordance with paragraph 3, or to have an appropriate reduction made in the price or the contract rescinded with regard to those goods, in accordance with paragraphs 5 and 6. (3) In the first place, the consumer may require the seller to repair the goods or he may require the seller to replace them, in either case free of charge, unless this is impossible or disproportionate. A remedy shall be deemed to be disproportionate if it imposes costs on the seller which, in comparison with the alternative remedy, are unreasonable, taking into account: - the value the goods would have if there were no lack of conformity, - the significance of the lack of conformity, and - whether the alternative remedy could be completed without significant inconvenience to the consumer. Any repair or replacement shall be completed within a reasonable time and without any significant inconvenience to the consumer, taking account of the nature of the goods and the purpose for which the consumer required the goods. (4) The terms "free of charge" in paragraphs 2 and 3 refer to the necessary costs incurred to bring the goods into conformity, particularly the cost of postage, labour and materials. (5) The consumer may require an appropriate reduction of the price or have the contract rescinded: - if the consumer is entitled to neither repair nor replacement, or - if the seller has not completed the remedy within a reasonable time, or - if the seller has not completed the remedy without significant inconvenience to the consumer. (6) The consumer is not entitled to have the contract rescinded if the lack of conformity is minor.*"

[75] The first part of the PECL dates from 1995, the second part from 1999 and the third from 2002.

[76] The PICC were first published in 1994 and have since been amended and extended several times.

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detail.[77] In addition, the PECL played an important role in the question of the incorporation of consumer law in the German Civil Code, in the liability of the debtor under § 276 BGB[78] and in particular in the reorganisation of the limitations rules under §§ 194ff. BGB.[79] The draft of the CESL (2011) and the DCFR (2009), on the other hand, have only played a minor role in reform efforts in Germany so far due to their considerably later date of origin compared to the PICC and PECL. Nevertheless, art. VI.-2:202(1) DCFR[80] was the inspiration for the creation of § 844(3) BGB,[81] which regulates the newly introduced survivorship claim ("*Angehörigenschmerzensgeld*").[82] However, a corresponding reference to the regulation of the DCFR cannot be found in the legislative materials, so that it can only be assumed that this is a case of covert comparative law.[83] In addition to the legal principles mentioned above, the German legislator is increasingly guided by model laws in drafting legislation which are at least in part based on comparative law. For example, in 1998, the tenth book of the Code of Civil Procedure ("*Zivilprozessordnung*" or "*ZPO")*) on arbitration proceedings (§§ 1025ff. ZPO) was largely based on the UNCITRAL Model Law on International Commercial Arbitration of 1985.

Let us then recapitulate: For the German legislator, comparative law has never been just a hobby, it has always been an integral part of contriving legislation. However, the points of reference for comparative law have changed. Attention is no longer focused only on foreign legal systems. It is increasingly turning to international uniform law and soft law instruments, which give comparative law as a whole greater weight and place it on a more solid foundation. This development can be observed particularly well with view to the reform of the law of obligations.

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[77] Bundestag-Drucksache 14/6040, 129.

[78] § 276 BGB reads: "*(1) The obligor is responsible for intention and negligence, if a higher or lower degree of liability is neither laid down nor to be inferred from the other subject matter of the obligation, including but not limited to the giving of a guarantee or the assumption of a procurement risk. The provisions of sections 827 and 828 apply with the necessary modifications. (2) A person acts negligently if he fails to exercise reasonable care. (3) The obligor may not be released in advance from liability for intention.*"

[79] Bundestag-Drucksache 14/6040, 92, 96, 131.

[80] Art. VI - 2:202(1) DCFR reads: "*Non-economic loss caused to a natural person as a result of another's personal injury or death is legally relevant damage if at the time of injury that person is in a particularly close personal relationship to the injured person.*"

[81] § 844(3) BGB reads: "*The person liable in damages must provide reasonable monetary compensation to a survivor, who at the time of the injury was in a particularly close personal relationship to the deceased, for the emotional distress caused to the survivor. A particularly close personal relationship is presumed if the survivor was the spouse, the civil partner, a parent or a child of the deceased.*"

[82] However, § 844(3) BGB is narrower, as a claim is only possible in the event of death, whereas under the DCFR, bodily injury may also suffice.

[83] See also C. von Bar, 'Review of the work Nils Jansen/Reinhard Zimmermann (eds.), Commentaries on European Contract Laws, Oxford: Oxford University Press, 2018' (2019) 219 *Archiv für die civilistische Praxis (AcP)* 594.

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The numerous references to the above-mentioned sources are intended to achieve as much "international decisional harmony" as possible. By means of comparative law, German law thus becomes a "bridging law" to other legal systems and is intended to place "*Law made in Germany*" at the forefront of international legal development.[84] And, carefully glancing at the distance future, one can even speculate that the newly designed BGB could be regarded a "transitional law" with a view to the creation of a possible future European Civil Code.[85]

6. Significance of comparative law for the interpretation of law by courts

The interpretation of the law is the sole responsibility of the courts.[86] In order to answer the question as to whether German courts are allowed to engage in comparative law analyses and whether such considerations actually take place, a distinction must be made between purely national cases (1.) and cases with references to international uniform law (2.).

6.1. Interpretation of national law

Let us first turn to the interpretation of purely national law. Traditionally, national private law in Germany is interpreted using four methods: grammatical, historical, systematic and finally objective-teleological interpretation, i.e. interpretation according to the spirit and purpose of the norm.[87] If then the legislator has worked in a comparative manner as described above, courts can fall back on referenced legal systems within the purview of a historical interpretation. This means, in turn, that the more the legislator uses comparative law and is outright about it, as for example in the reform of the law of obligations, the easier it is for courts to include comparative law arguments in their legal reasoning. The legislator's comparative law approach thus makes it easier for the courts to utilise comparative law arguments themselves; in this respect, the legislator "opens the door" for the courts, so to speak.

[84] The German legislator also wanted to create a modern and competitive law of obligations. For a general description of this basic idea for German private and commercial law see the brochure "*Law: Made in Germany*" by the Federal Ministry of Justice and Consumer Protection, available at https://www.lawmadeingermany.de/Law-Made_in_Germany_EN.pdf.
[85] On the idea of a European Civil Code see already D. Martiny, N. Witzleb (eds.), *Auf dem Weg zu einem Europäischen Gesetzbuch* (Berlin: Springer, 1999).
[86] See in more detail for example B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 69.
[87] See F. K. von Savigny, *System des heutigen römischen Rechts*, volume 1 (Berlin: Veit, 1840) 212.

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Since *Konrad Zweigert*'s 1949 fundamental essay entitled "*Rechtsvergleichung als universelle Interpretationsmethode*" ("*Comparative law as a universal method of interpretation*"),[88] the crucial question for legal interpretation has become whether comparative law interpretation should be recognised as the "*fünfte Auslegungsmethode*") ("*fifth method of interpretation*") in addition to the four traditional methods mentioned above. This would allow general recourse to findings of comparative law, i.e. even if the legislative history does *not* contain any comparative law references.[89] To this end, it must first be clarified whether a comparative law interpretation is at all permissible under German law, and, second, to what extent the courts already make actual use of comparative law (in the sense of a fifth method of interpretation?) when interpreting German law.

6.1.1. Admissibility of comparative law for the interpretation of national law

The Federal Constitutional Court ("*Bundesverfassungsgericht"*) has repeatedly stated that German law does not prescribe *how* the courts arrive at their decisions. Referring to article 20(3) of the Basic Law ("*Grundgesetz"*),[90] the Court states that judges are held to decide only in accordance with the law, without prescribing a particular method of interpretation.[91] It expressly considers the use of the comparative law method to be permissible. To this end, it has stated in one of its very first decisions:

> "*Moreover, the courts have made use of tried and tested tools, namely interpretation and gap-filling, and have also applied the comparative law method.*" [92]

Despite these clear words, there is reluctance or maybe even profound scepticism among the other German Federal Courts with regard to the use of foreign legal materials for the interpretation of national law. For example, the Federal Court of Justice has stated that[93] comparative law can only have a limited value in the interpretation of national law and the Federal Administrative Court

[88] K. Zweigert, 'Rechtsvergleichung als universale Interpretationsmethode' (1949/50) 15 *Rabel Zeitschrift für ausländisches und internationales Privatrecht (RabelsZ)* 1, 8.
[89] If foreign law is applicable as a result of the conflict of laws, the judge can of course, according to § 293 ZPO, easily refer to foreign sources and judgments.
[90] Art. 20(3) Basic Law reads: "*The legislature shall be bound by the constitutional order, the executive and the judiciary by law and justice.*"
[91] Bundesverfassungsgericht, Entscheidungen des Bundesverfassungsgerichts (BVerfGE) 88, 145.
[92] Bundesverfassungsgericht, Entscheidungen des Bundesverfassungsgerichts (BVerfGE) 3, 225, 244. In German it reads as follows: "*Im Übrigen haben die Gerichte sich der erprobten Hilfsmittel, nämlich der Interpretation und Lückenfüllung, unter Verwertung auch der rechtsvergleichenden Methode bedient.*"
[93] Bundesgerichtshof, Entscheidungen des Bundesgerichtshofs in Zivilsachen (BGHZ) 86, 240, 250.

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("*Bundesverwaltungsgericht*") equally emphasised that jurisprudence is a "*nationally influenced science*".[94]

6.1.2. Status quo of comparative law in the interpretation of national private law

However, the above-mentioned does not mean that comparative law considerations are completely unknown to the courts when interpreting German private law. For the period from 1909 to 1928, no less than 17 judgments of the German Imperial Court ("*Reichsgericht*") can be found that contain comparative law references.[95] Most of the decisions concerned legal aspects of company law. *Hein Kötz* counts at least 14 judgments with comparative law considerations by the Federal Court of Justice before the year 2000.[96] For example, in interpreting § 616 BGB (temporary prevention from performing services),[97] the Federal Court of Justice used the Swiss Code of Obligations ("*Obligationenrecht*") to assess whether the injuring party must pay damages for loss of earnings even if the injured party continues to receive a renumeration.[98] For the interpretation of § 89b(1) of the German Commercial Code ("*Handelsgesetzbuch*")[99] the court referred to provisions of Italian, French and especially Swiss law with regard to the transfer of a compensation claim of a commercial agent to his widow.[100]

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[94] Bundesverwaltungsgericht, Neue Juristische Wochenschrift (NJW) 1993, 276. In German it reads as follows: "*national geprägte Wissenschaft*".

[95] B. Aubin, 'Die rechtsvergleichende Interpretation autonom-internen Rechts in der deutschen Rechtsprechung', (1970) 34 *Rabel Zeitschrift für ausländisches und internationales Privatrecht* (RabelsZ) 458.

[96] H. Kötz, 'Der Bundesgerichtshof und die Rechtsvergleichung' in C. W. Canaris, A. Heldrich, K. Schmidt, C. Roxin, G. Widmaier (eds.), *50 Jahre Bundesgerichtshof* (Munich: Beck, 1999) 825, 832. As far as can be seen, further investigations in this area, which cover the period thereafter, are unfortunately not available.

[97] § 616 BGB reads: "*The person obliged to perform services is not deprived of his claim to remuneration by the fact that he is prevented from performing services for a relatively trivial period of time for a reason in his person without fault on his part. However, he must allow to be credited against him the amount he receives for the period when he is prevented under a health or accident insurance policy that exists on the basis of a statutory duty.*"

[98] Bundesgerichtshof, Entscheidungen des Bundesgerichtshofs in Zivilsachen (BGHZ) 21, 112, 119.

[99] § 89b(1) German Commercial Code reads: "*The commercial agent shall be entitled to demand a reasonable indemnity from the principal, after termination of the agency contract, if and to the extent that 1. the principal continues to derive substantial benefits, even after termination of the agency contract, from business relations with new customers brought by the commercial agent, and 2. the payment of an indemnity is equitable having regard to all the circumstances and, in particular, the commission lost by the commercial agent on the business transacted with such customers. If the commercial agent has so significantly increased the volume of business with a customer that it is economically equivalent to the acquisition of a new customer, it shall be deemed equal to the acquisition of a new customer.*"

[100] Bundesgerichtshof, Entscheidungen des Bundesgerichtshofs in Zivilsachen (BGHZ) 24, 214, 218. See also B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 70.

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Tort law is an important focus of the courts' usage of comparative law.[101] The significant case law on compensation for immaterial damage in the case of violations of personality rights is based (in part) on comparative law considerations. As early as 1961, in the famous *ginseng root case,* the Federal Court of Justice used Swiss law, more precisely art. 49(1) of the Swiss Code of Obligations (which has since been revised), to emphasise the satisfaction function ("*Genugtuungsfunktion*") of immaterial damages in the case of violations of personality rights.[102] In the equally well-known *tv announcer's case* that was rendered a few years later, the Court based the same result on more far-reaching and general comparative considerations. It argued that "*in almost all legal systems in which (…) the personal value of the individual is of central importance, immaterial damages are recognised as the sanction under private law adequate to the violation of the right of personality*".[103] Further, in the *wrongful life case*[104] of 1983, the Federal Court of Justice referred extensively to relevant U.S. case law as well as, in particular, to the English case *McKay v. Essex Health Authority*[105] and finally dismissed the complaint of a severely disabled child against a physician, refusing to apply the categories of "*wrongful life*" or "*wrongful birth*".

In evaluating the judgments of the Federal Court of Justice, the conclusion can be drawn that the Court resorts to comparative law considerations only very selectively.[106] This, in turn, illustrates that the idea of using comparative law as a genuine fifth interpretative method has not (yet) been able to assert itself. The brief explanations also show, albeit not on an empirical basis, how rarely comparative law comes into play at the Federal Court of Justice for the purpose of interpreting national law. Furthermore, it becomes apparent that even where comparative law considerations are relied on, they usually take on a secondary role for the specific decision. In most of the examined judgments, it appears that the judges had already come to a decision by other means and only added references to foreign law afterwards in order to increase the persuasiveness of the judgment. Consequently, the Federal Court of Justice makes use of comparative law, above all, with view to its

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[101] One of the reasons for this is that there is a relative lack of norms in German tort law, and in particular § 823(1) BGB and §§ 249ff. BGB are particularly suitable as gateways for comparative law considerations.

[102] Bundesgerichtshof, Entscheidungen des Bundesgerichtshofs in Zivilsachen (BGHZ) 35, 363, 369.

[103] Bundesgerichtshof, Entscheidungen des Bundesgerichtshofs in Zivilsachen (BGHZ) 39, 124, 132. In German it reads as follows: „*In fast allen Rechtsordnungen, in denen entsprechend unserer Auffassung dem Personenwert des Einzelnen eine zentrale Bedeutung im Rechtssystem zukommt, der immaterielle Schadensersatz als die der Persönlichkeitsrechtsverletzung adäquate privatrechtliche Sanktion anerkannt.*"

[104] Bundesgerichtshof, Entscheidungen des Bundesgerichtshofs in Zivilsachen (BGHZ) 86, 240ff.

[105] *McKay v. Essex Health Authority* [1982] 2 WLR 890.

[106] Likewise with this judgment B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 46.

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control and confirmation function and, less frequently, its contrasting function[107] - if it makes use of comparative law considerations at all.[108] Hence, comparative law does not generally play a decisive role in the interpretation of national law. The use of comparative law is regarded by judges as a possible expedient, but also a purely optional venture. Further, and this is not intended to be a general scolding of judges, a comparative analysis will often prove unfeasible in practice due to a judicial lack of time, language skills and access to trustworthy sources of law.[109]

However, and this factor should not be underestimated, the "flow" of comparative law is not simply linear.[110] German jurisprudence, for instance, relies heavily on German legal literature, which in turn has thoroughly processed and absorbed foreign legal concepts.[111] In this way, foreign law influences the interpretation of national law, even though the courts themselves do not make use of a comparative method.[112] *Bernhard Großfeld*, who finds it difficult to accept comparative law as a fifth method of interpretation in the sense of *Konrad Zweigert*, considers this to be the preferable path to head down:

> "*It is generally better to run comparative law through the filter of legal literature. As part of a creative jurisprudence, science thus fulfils its most beautiful task: to think ahead of practice and show the way to the future.*" [113]

6.2. International uniform law

In his fundamental habilitation thesis "*Internationales Einheitlichrecht*" ("*International Uniform Law*"),[114] *Jan Kropholler* adresses the question of interpretation in the context of international uniform law:

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[107] Examples of the use of this contrast function of comparative law can be found in Bundesgerichtshof, Neue Juristische Wochenschrift (NJW) 1981, 1206ff. (unethicality of instalment loans) and Bundesgerichtshof, Entscheidungen des Bundesgerichtshofs in Zivilsachen (BGHZ) 86, 240ff. (damages for wrongful life and wrongful birth respectively).

[108] B. Markesinis, J. Fedtke (n. 14) 173.

[109] A similar assessment is made by B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 35.

[110] For further details see B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 71; B. Markesinis, J. Fedtke (n. 14) 170.

[111] On the question which authors or which works the Federal Court of Justice cites see B. Markesinis, J. Fedtke (n. 14) 175.

[112] It goes without saying, however, that direct proof is difficult to provide to this end.

[113] B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 36. In German, it reads as follows: "*Es ist im Allgemeinen besser, die Rechtsvergleichung durch den Filter der Literatur laufen zu lassen. Die Wissenschaft erfüllt damit als Teil einer schöpferischen Jurisprudenz ihre schönste Aufgabe: Der Praxis vorzudenken und den Weg in die Zukunft zu weisen.*"

[114] J. Kropholler, *Internationales Einheitsrecht* (Tübingen: Mohr Siebeck, 1975) 280.

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> "*The foreign case law and literature on the text of the uniform law subject to interpretation must be observed without fail, because without this cross-border perspective the desired uniformity in international legal development cannot be achieved.*" [115]

The German courts take this demand into account, at least to a large extent, when interpreting international uniform law.[116] This applies, for example, to the interpretation of international transport and maritime law, where the Federal Court of Justice regularly refers to foreign judgments and literature.[117] Also, in the area of international sales law, i.e. the CISG, the Court refers to foreign literature and case law, as for example a decision from 2004 reveals.[118] In this case, several Dutch and Canadian arbitral decisions were explicitly referred to in order to solve questions regarding the burden of proof. The questions concerned the seller's knowledge or grossly negligent ignorance of the lack of conformity of the delivered goods within the scope of art. 40 CISG.[119] In a decision of 2014, the Federal Court of Justice[120] referred to case law of the Swiss and Austrian Federal Court of Justice to determine a fundamental breach of contract under art. 25 CISG[121] and to answer the related question of contract avoidance under art. 49 CISG.[122] This much greater

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115 In German, it reads as follows: "*Die ausländische Rechtsprechung und Lehre zum auszulegenden Text des Einheitsrechts ist unbedingt zu beachten, weil ohne diesen Blick über die Grenzen die gewünschte international einheitliche Rechtsentwicklung nicht möglich ist.*"

116 See also and with some statistics B. Markesinis, J. Fedtke (n. 14) 165.

117 Bundesgerichtshof, Entscheidungen des Bundesgerichtshofs in Zivilsachen (BGHZ) 88, 157, 160; Bundesgerichtshof, Neue Juristische Wochenschrift (NJW) 1976, 1583, 1584. In the area of conflict of laws German case law traditionally refers relatively often to foreign judgments and literature anyway.

118 Bundesgerichtshof, Neue Juristische Wochenschrift (NJW) 2004, 3181.

119 Art. 40 CISG reads: *"The seller is not entitled to rely on the provisions of articles 38 and 39 if the lack of conformity relates to facts of which he knew or could not have been unaware and which he did not disclose to the buyer."*

120 Bundesgerichtshof, Neue Juristische Wochenschrift (NJW) 2015, 867.

121 Art. 25 CISG reads: "*A breach of contract committed by one of the parties is fundamental if it results in such detriment to the other party as substantially to deprive him of what he is entitled to expect under the contract, unless the party in breach did not foresee and a reasonable person of the same kind in the same circumstances would not have foreseen such a result.*"

122 Art. 49 CISG reads: "*(1) The buyer may declare the contract avoided: (a) if the failure by the seller to perform any of his obligations under the contract or this Convention amounts to a fundamental breach of contract; or (b) in case of non-delivery, if the seller does not deliver the goods within the additional period of time fixed by the buyer in accordance with paragraph (1) of article 47 or declares that he will not deliver within the period so fixed. (2) However, in cases where the seller has delivered the goods, the buyer loses the right to declare the contract avoided unless he does so: (a) in respect of late delivery, within a reasonable time after he has become aware that delivery has been made; (b) in respect of any breach other than late delivery, within a reasonable time: (i) after he knew or ought to have known of the breach; (ii) after the expiration of any additional period of time fixed by the buyer in accordance with paragraph (1) of article 47, or after the seller has declared that he will not perform his obligations within such an additional period; or (iii) after the expiration of any additional period of time indicated by the seller in accordance with paragraph (2) of article 48, or after the buyer has declared that he will not accept performance.*"

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consideration of foreign judgments and literature compared to the interpretation of national law is understandable, among other things, because the conventions of international uniform law contain standards such as art. 7(1) CISG[123] which require a uniform international application and thus the use of foreign case law and literature.[124] Nevertheless, this conclusion must not obscure the fact that there is no room for a comparative legal interpretation in international uniform law by reference to national law, since this approach would downright contradict the required uniform and international application.[125] A limited possibility of referring to foreign legal systems may only arise where the drafting history of the international uniform law expressly refers to them as a model.

Conclusion

So what is the significance of comparative law in 21st century Germany? Is it just a hobby taken on by a few bored academics, merely a "*collection of building blocks in a heap on which they are left lying unused*",[126] or is it one of the supporting pillars of the German private law landscape? The result varies depending on the field examined. Comparative law is of very little importance in the area of legal practice, at least as long as the specific case does not exhibit any international connection. Its importance within legal education can be considered somewhat higher, although there is a clear need for improvement here. Points of criticism are, in particular, the failure to schedule comparative law as a compulsory subject as well as the inadequate systematic integration into lectures on other parts of private law. Comparative law remains more of a foreign body than an integral component in legal education.

On the other hand, the importance of comparative law within legal research and legislation in Germany is significant. Here, comparative law is certainly not a leisurely exercise, but rather takes on a central position. Especially in the field of legislation, the importance of comparative law seems to have increased significantly in the last two decades, in line with *Lord Goff's* predictions. In part, this is due to the numerous references to international uniform law, in particular the CISG, and to comparative

[123] Art. 7(1) CISG reads: "*In the interpretation of this Convention, regard is to be had to its international character and to the need to promote uniformity in its application and the observance of good faith in international trade.*"

[124] The German-language commentaries on the CISG are regularly used instead or in addition, all of which have deal extensively with foreign case law and literature. See e.g. I. Schwenzer, P. Schlechtriem, U. Schroeter (eds.), *Kommentar zum einheitlichen UN-Kaufrecht – CISG,* (7th edition, Munich: Beck, 2019).

[125] Similar F. Ferrari, 'Art. 7 CISG', in I. Schwenzer, P. Schlechtriem, U. Schroeter (eds.), *Kommentar zum einheitlichen UN-Kaufrecht – CISG* (n. 124) 40.

[126] B. Großfeld, *Macht und Ohnmacht der Rechtsvergleichung* (n. 2) 18. In the original German version it reads as follows: "*Ansammlung von Bausteinen auf einem Haufen, auf den sie ungenutzt liegenbleiben*".

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legal principles such as PECL and PICC. These references seem to go beyond the mere update of national law, they indicate an attempt to create an even stronger decisional harmony with the rest of the world. This can be seen for example in the reform of the law of obligations. Here, among other objectives, the legislator is attempting to bridge the gap to other legal systems, maybe even with a possible European Civil Code in mind in the very long run.

The most difficult endeavour is certainly determining the true significance of comparative law for the interpretation of national law by the courts.[127] The Federal Court of Justice itself, despite expressing some scepticism, relies on comparative law considerations from time to time. However, it does not do so systematically and, ultimately, the use of comparative law seems somewhat arbitrary. The Federal Court of Justice has never been able to bring itself to recognise comparative law as a genuine fifth method of interpretation. However, since the legislator is making use of comparative law more and more, the courts will be provided with increasing opportunities to resort to comparative law arguments within the framework of the historical interpretation.[128] It should also be borne in mind that German courts make intensive use of literature in their decisions, which in turn has often incorporated comparative law considerations. In the longer term, however, and in order to clarify the significance of comparative law for the interpretation of the law, a fundamental clarification by the Federal Court of Justice appears desirable. Despite the understandable difficulties in taking comparative law into account, the German courts, and ultimately all German lawyers, should lend an ear to *Lord Goff* when he reflects on the general role of comparative law: "*We must welcome rather than fear its influence.*"[129]

[127] This applies only in part to the interpretation of international uniform law, as shown above.

[128] A good example for this development is the decision of the Federal Court of Justice from 2012 (see Bundesgerichtshof, Neue Juristische Wochenschrift (NJW) 2012, 3714). For the interpretation of the German provision dealing with the anticipatory breach (§ 324(4) BGB) the judges used literature and case law on the CISG, as art. 72 CISG was the model after which the German provision was drafted.

[129] R. Goff (n. 1) 745, 748.

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