

Maria Alessandra Stefanelli

European SMEs and the Digital Single Market

The Dynamics
of New Regulation

FrancoAngeli 

Collana

di Diritto

SAGGI E RICERCHE



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European SMEs and the Digital Single Market

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1. Micro, small, and medium-sized businesses and new globalization. Digital challenges in the pandemic and post-pandemic contexts in the international marketplace

SUMMARY: 1. Smaller Enterprises and the New Globalization: Challenges and Opportunities in the Analyses and Surveys of Major International Organizations. The International Monetary Fund – 2. The World Bank – 3. The Organisation for Economic Co-operation and Development – 4. The World Trade Organization.

1. Smaller Enterprises and the New Globalization: Challenges and Opportunities in the Analyses and Surveys of Major International Organizations. The International Monetary Fund

The pandemic and the conflicts currently taking place globally have undoubtedly made the world very different from that we had known, studied, and analyzed previously.

These changes have been radical and profound; there seems to be no sign of return to the status quo ante.

These changes can be described as “epochal” and include digitalization.

They have had a disruptive impact on society, law, and the market; therefore, economic law scholars must reconsider traditionally used legal categories and institutions.

Scholars have effectively demonstrated how the law has long since entered the age of technology, with problems arising from applying legal techniques to the world of technology and the Internet in particular. Today, one could reformulate the ancient Latin proverb as “ubi societas tecnologica, ibi ius”¹.

1. T.E. Frosini, *Il costituzionalismo nella società tecnologica*, in *Diritto dell'informazione e dell'informatica*, 2020, p. 465. On this point also see by the same author, *Orizzonte giuridico della intelligenza artificiale*, in *Dir. Inf.*, 2022, p. 9, where it is emphasized that currently, the new frontiers of law and rights are represented by the enormous capacity to collect and process data to produce algorithms capable of finding intelligent solutions to problems; data that concern not only people but also goods, services, means, and productive capacity that can be exchanged

Now, we are seeing the figure of the traditional jurist transform into that of a technological jurist, whose task is to be an interpreter of societal transformations and the impact of technology on law and rights².

Digitalization has highlighted critical issues of the more traditional forms of capitalism in modern Western democracies, including the ineffectiveness of traditional legal regulation of economic activities in the digital market.

Nonetheless, the digital market seems closer to meeting the challenge of the rapidly changing economy and the new social challenges that increasingly inform the decisions of consumers and entrepreneurs. In these days, the term “digital entrepreneurship” has become popular, generally understood as “the process of entrepreneurial creation of digital value through the use of various socio-technical digital enablers to support effective acquisition processing, distribution, and consumption of digital information”³.

The United Nation’s (UN)⁴ environmental societal governance (ESG)

to create a real data market. For the legal doctrine, see the studies by N. Zorzi Galgano (a cura di), *Le due anime del GDPR e la tutela del diritto alla privacy*, in *Persona e mercato dei dati. Riflessioni sul GDPR*, Padova, 2019, p. 35 ss.; G. Alpa, *Diritto ed intelligenza artificiale: profili generali, soggetti, contratti, responsabilità civile, diritto bancario e finanziario, processo civile*, Pisa, 2000; L.S. Rossi, *Brevi osservazioni sulle recenti tendenze evolutive della Corte di Giustizia europea sulla protezione dei dati personali*, in *Euroius*, 2020, p. 51 ss.; G. Finocchiaro, *Il Regolamento (UE) 2016/679 relativo alla protezione delle persone fisiche con riguardo al trattamento dei dati personali, nonché alla libera circolazione di tali dati*, in A. Ciriello, G. Grasso, D. Lo Moro (a cura di), *Il trattamento dei dati personali in ambito giudiziario*, Scuola Superiore della Magistratura, Roma, 2021, pp. 19 ss.; M. Palmirani, *Un ordine legale intelligente per l’era digitale: intelligenza artificiale ibrida e un modello dialogico*, in *Ragion pratica*, 2022, p. 633 ss.; L. Golisano, *Il governo digitale: strutture di governo e innovazione digitale*, in *Giornale di diritto amministrativo*, 2022, p. 824 ss.; F. Bravo, *Data Management Tools and Privacy by Design and by Default*, in R. Senigaglia, C. Irti, A. Bernes (eds.), *Privacy and Data Protection in Software Services*, Singapore, 2022, p. 85 ss.

2. T.E. Frosini, *Il costituzionalismo nella società tecnologica*, in *Diritto dell’informazione e dell’informatica*, p. 465, observes that new rights are emerging; although they do not possess their own explicit recognition, they nevertheless have a strong constitutional tone.

3. J.M. Sahut, L. Iandoli, F. Teulon, *The age of digital entrepreneurship*, in *Small Business Economics*, 2021, p. 1162, which follows by saying “This definition can be extended and applied to specific types of ventures such as nascent ventures and digital self-employment... Technologies such as social media, open-source, software and hardware, crowdfunding, e-trust and online reputation assessment, 3D printing, digital imaging and big data are empowering would-be entrepreneurs to reduce significantly the barriers between invention and the creation of a new company (Steininger 2019)”.

4. See for all, S. Arvidsson, J. Dumay, *Corporate ESG reporting quantity, quality and performance: Where to now for environmental policy and practice?*, in *Business Strategy and the Environment*, 2022, p. 1091 ss.; A. Clément, E. Robinot, L. Trespeuch, *Improving ESG Scores With Sustainability Concepts*, in *Sustainability*, 2022, p. 1 ss.; N. Ellili, *Impact of ESG disclosure and financial reporting quality on investment efficiency*, in *Corporate Governance*, 2022, p. 109 ss.

objectives contain important examples for creating fair and sustainable legal and economic relations to build new markets and social orders.

Therefore, digitalization has marked a watershed between the old and new worlds, overshadowing the academic debate on the relationship between the state and the market that characterized the 1980s⁵, such that any thoughts on the relationship between public power and private actors cannot be separated from specific lessons⁶.

The first lesson is that a centrally planned economy does not work. The second is that pure market systems do not actually exist⁷; practically speaking, such economic models have not been successful in creating economic prosperity for large sections of the population (the market economy model) or for the entire population (the centralized economy and planning model).

Thus, the traditional “state vs. market” debate should be reconsidered in light of a combination of the two models^{8,9}.

Digitalization plays a prominent role in generating a new awareness of the economic and social environment businesses operate in.

Therefore, any legal reflections on the market must consider the revolution in information technology that characterizes economic relations and trade today.

Hence, reference is made to digital capitalism and an “informational economy”, which are a particular form of contemporary capitalism that regard information as the benchmark of all production, economic, and financial processes¹⁰.

5. P. De Grauwe, *I limiti del mercato. Da che parte oscilla il pendolo dell'economia?* Bologna, 2014, p. 7.

6. *Ibidem*.

7. *Ibidem*, which makes it clear that, in reality, all economic systems known to date can be considered as a composite set of market and State public control.

8. *Ibidem*.

9. J.E. Stiglitz, *L'Euro. Come una moneta comune minaccia il futuro dell'Europa*, Torino, 2017, p. 22, recalls that market fundamentalism started from the assumption that markets were naturally efficient and stable. It indicates that the founder of this school of thought, Adam Smith, did not support this but the exact opposite, on the assumption that the state was assigned to play a fundamental role in the economy; and indeed, the economic doctrine has, over time, shown that markets cannot be efficient and stable per se. Stiglitz also notes that the idea behind the model of perfect markets had already been disproven by the theory of the second best, developed by economists James Meade, Kevin Lancaster, and Richard Lipsey. In general, see also G. Ghetti, *Lineamenti di diritto pubblico dell'economia*, Milano, 2001; R. Sennet, *La cultura del nuovo capitalismo*, Bologna, 2006; P. Bowles, *Il Capitalismo*, Bologna, 2007. More recently, see C. Crouch, *Salviamo il capitalismo da se stesso*, Bologna, 2018; N. Fraser, *Capitalismo. Una conversazione con Raphael Jaeggi*, Milano, 2019; J.E. Stiglitz, *Popolo, potere e profitti*, Torino, 2020; B. Milanovic, *Capitalismo contro capitalismo. La sfida che deciderà il nostro futuro*, Bari, 2020; K. Pistor, *Il Codice del capitale*, Roma, 2020.

10. E. Maestri, *Lex informatica. Diritto, persona e nell'età del cyberspazio*, Napoli, 2015, p. 43.

Information is the pulse of the informational economy and the center of production processes and analysis in economic science. Meanwhile, in the field of legal science, it is of genuinely epochal significance because some concepts, such as sovereignty, law, privacy, the person, and fundamental rights, undergo a semantic shift within the new digital technological sphere where space and time do not exist, and everything occurs in real-time.

In this changed context, law becomes “lighter”, decomposing and delocalizing itself, like the bits of a file¹¹.

Concerning the complex subject of digital information, thanks to information and communications technology (ICT), we have entered the “age of the zettabyte”, a neologism describing the “tsunami” of data created every day.

Thus, the current generations are experiencing a transition from history to hyperhistory, a new era of human development, and the creation of an infosphere¹².

The digitalization of markets has led to a new “configuration” of the traditional concept of the entrepreneur, who now faces multiple new possibilities inherent in “new globalization”¹³ that is, the revolutionary changes brought about by ICT are prompting scholars of economic law, in particular, to reflect on the need to construct new rules for businesses, especially smaller ones.

As written in the doctrine, globalization is a phenomenon in continuous transformation that occurs in a non-linear fashion and has been gathering strength since the birth of capitalism.

The term can be traced back at least to 1860, if not to the end of the Napoleonic wars and the Pax Britannica.

Since the Second World War, the regulation of economic relations at an international level has been governed by organizations following the principles of multilateralism.

Almost all current international economic organizations can be regarded as belonging to the UN “family”.

11. Ivi, p. 44.

12. L. Floridi, *La Quarta rivoluzione. Come l'infosfera sta trasformando il mondo*, Milano, 2014, pp. 25-26, who observes how the term infosphere (a neologism that originated in the 1970s and is analogous to a “biosphere”, that is, that part of our planet characterized by life) refers, at a minimum level, to an informational environment produced by all the informational entities in their reciprocal relations. At a maximum level, the term is used as a synonym for reality interpreted in informational terms (p. 45). See by the same author, *Infosfera. Etica e filosofia nell'età della informazione*, Torino, 2009 and, *Pensare l'infosfera. La filosofia come design concettuale*, Milano, 2020.

13. See S. Cassese, *Chi governa il mondo?*, Bologna, 2013; by the same author see also *Il diritto globale. Giustizia e democrazia oltre lo Stato*, Torino, 2009, and *Lo spazio giuridico globale*, Roma-Bari, 2006.

The most important of these organizations at the economic level include, for this study, the International Monetary Fund (IMF), the World Bank (WB), the Organisation for Economic Co-operation and Development (OECD), and the World Trade Organization (WTO)¹⁴.

These organizations, which regulate economic activities, specifically focus on smaller enterprises, as we shall see in this chapter.

Small- and medium-sized enterprises (SMEs), or micro, small, and medium-sized enterprises (MSMEs), represent the most widespread form of entrepreneurship worldwide; the most recent estimates register their presence across the globe¹⁵.

According to estimates from the WB, “SMEs play a major role in most economies, particularly in developing countries. SMEs account for most businesses worldwide and are important contributors to job creation and global economic development. They represent about 90% of businesses and more than 50% of employment worldwide. Formal SMEs contribute up to 40% of the national gross domestic product (GDP) in emerging economies. These numbers are significantly higher when informal SMEs are included. According to our estimates, 600 million jobs will be needed by 2030 to absorb the growing global workforce, making SME development a high priority for many governments worldwide. In emerging markets, most formal jobs are generated by SMEs, which create 7 out of 10 jobs”¹⁶.

At the international level, the IMF directed and controlled the conduct of member states regarding the exchange rate regime and fostered the free development of international trade¹⁷.

In particular, concerning the new digital environment within which the economies of individual states operate, the IMF points out that “since the start of the 2000s, a new fast-growing phenomenon is changing our societies: digitalization. The digitalization of economic activity can be broadly defined

14. E. Sciso, *Appunti di diritto internazionale dell'economia*, Torino, 2021, p. 8, recalls how in the post-Second World War period, international economic relations were inspired by neo-liberal principles or the so-called guaranteed liberalism, where the free play of the market is controlled by international organizations to regulate the activities of states and other economic subjects through the issuing of specific rules of conduct. Immediately after the Second World War, the economically strongest countries, namely the United States and Great Britain, set out to create a system of international relations ranging from the political to the economic, financial, and trade spheres; therefore, two separate agreements were signed at the Bretton Woods Conference to establish two international economic and financial organizations, the International Monetary Fund and the World Bank.

15. The World Bank, *SME finance*, 2022, p. 1.

16. *Ibidem*.

17. E. Sciso, *Appunti di diritto internazionale dell'economia*, Torino, 2021, p. 28.

as the incorporation of data and the Internet into production processes and products, new forms of household and government consumption, fixed-capital formation, cross-border flows, and finance”¹⁸.

It goes on to state that the digital economy “is sometimes defined narrowly as online platforms and activities that owe their existence to such platforms; yet, in a broad sense, all activities that use digitized data are part of the digital economy: in modern economies, the entire economy”¹⁹.

In this new and unprecedented scenario, “a new breed of “superstar” firm has come to the fore of global markets over the last decade. These are businesses at the vanguard of the so-called ‘digital revolution’, in which technology is being harnessed to redefine traditional business models, provide new ways for buyers and sellers to interact both locally and globally, and support flexible working arrangements. Many of these ‘tech giants’ are capitalizing on first-mover advantages and network externalities to boost profitability, secure market dominance, and become some of the world’s most highly valued companies”²⁰.

Digital transformation involves one of the key issues for smaller enterprises, that is, access to a source of finance that “affects them disproportionately more than large firms”. In particular, “studies find that banks in developing economies, compared to those in developed economies, tend to be less exposed to SMEs and charge them higher interest rates and fees (Beck et al., 2008). This has been largely due to three factors: (i) informational asymmetries related to SMEs that create risks, e.g., banks are mostly unable to gauge the creditworthiness of SMEs and thus ask for higher charges and collateral requirements; (ii) low revenue per client; and (iii) the need for local presence, and thus for a large branch network, which may not necessarily be optimal from a cost perspective, especially in a developing country setting”²¹.

In this regard, the IMF highlights the role that digitalization can play in facilitating access to finance and the growth of smaller companies, especially for the Middle Eastern regions, North Africa, Afghanistan, and Pakistan (MENAP) and the Caucasus and Central Asia (CCA), highlighting that “both capital markets and fintech are still nascent in the MENAP and CCA regions. A range of policies and reforms have already been implemented across countries to support SME financial inclusion. These include direct interventions to

18. IMF, *Measuring the digital economy*, 2018, p. 6.

19. Ivi, p. 7.

20. A. Aslam, A. Shah, *Tec(h)tonic shifts: Taxing the “digital economy”*, in *IMF Working Papers*, 2020, p. 5.

21. P. Stein, O. Ardic, M. Hommes, *Closing the credit gap for formal and informal micro, small, and medium enterprises*, International Finance Corporation, The World Bank Group, 2013, p. 11.

enhance bank credit, such as through state-owned SME banks, credit guarantee schemes, and interest rate regulations. In recent years, a growing number of countries have also developed national strategies to address key obstacles to household and firm financial inclusion”²².

Regarding difficulties that smaller companies may face in accessing finance, the IMF indicates that new digital services attributable to financial technology (fintech) are playing an increasingly important role for these companies: “Fintech is changing SME financing and has generated growing interest among policymakers development in recent years illustrates the potential of fintech as an alternative source of financing. In the United Kingdom, for instance, four banks accounted for 80% of SME lending before the global financial crisis. In response, the authorities required banks that denied credit to SMEs to refer them to alternative lending providers”²³.

The IMF mentions the following among the new fintech solutions available: “P2P/Marketplace (online platforms that collect contributions from investors toward business loans); equity-based crowdfunding (online platforms that allow individuals or institutional investors to purchase equity issued by a business); reward donation-based crowdfunding (online platforms that allow individual or institutional investors to provide funds in exchange for non-monetary rewards, products, or philanthropic motives); balance sheet business lending (online platforms that lend directly to businesses from their balance sheet); invoice lending (online platforms that provide liquidity to businesses in the form of (discounted) payments for outstanding customer invoices); merchant and e-commerce finance (online platforms that do not have lending as a core business, but have rich information about the customer base that they could potentially use to provide credit products)”²⁴.

The new digital financing opportunities for smaller companies are interesting in terms of the public legal regulations to which they are subjected.

Of particular interest is Regulatory Technology (Regtech), which is a “contraction of regulatory and technology and describes the use of technology, particularly information technology (IT), for regulation, monitoring, reporting, and compliance”²⁵.

We expand upon Regtech later in this study, focusing on how new digital technologies “can help lower regulatory compliance costs, a key obstacle to

22. N. Blancher, *Financial Inclusion of Small and Medium-Sized Enterprises in the Middle East and Central Asia*, in *International Monetary Fund Departmental Papers*, 2019, p. 6.

23. Ivi, p. 23.

24. Ivi, p. 28.

25. R.P. Buckley, D.W. Arner, D.A. Zetzsche, R.H. Weber, *The road to RegTech: the (astonishing) example of the European Union*, in *Journal of Banking Regulation*, 2020, p. 26.

SME credit. Many banks in the MENAP and CCA regions need to perform AML/CFT diligence for new accounts, which makes servicing SME accounts costlier. Fintech solutions offered by companies, such as Suede and BearingPoint (Abacus), can reduce these and other compliance costs by embedding regulatory requirements into IT protocols and allowing for real-time compliance monitoring. Know your customer and AML/CFT procedures can also be made more efficient by analyzing digitalized client and partner transaction data and writing contracts on distributed ledgers (Truiloo)²⁶.

To analyze this situation, where small businesses play an essential role, we should observe how “a tentative recovery in 2021 has been followed by increasingly gloomy developments in 2022 as risks began to materialize. Global output contracted in the second quarter of this year owing to downturns in China and Russia, while US consumer spending undershot expectation”. In fact, “several shocks have hit a world economy already weakened by the pandemic: higher-than-expected inflation worldwide, especially in the United States and major European economies, triggering tighter financial conditions; a worse than anticipated slowdown in China, reflecting Covid-19 outbreaks and lockdowns; and further negative spillovers from the war in Ukraine”²⁷.

In other words, “as noted, growth revisions for major advanced economies in 2022-2023 are generally negative”, particularly in Europe: “Real GDP for emerging and developing Europe is expected to shrink by 1.5% in 2022 than predicted in the April 2022 World Economic Outlook, with growth by 4.0% less in 2023”²⁸.

The Covid-19 pandemic profoundly impacted business activities of companies, with a disproportionate and catastrophic impact on small businesses.

This effect is highlighted by studies showing how small businesses “are confronted with various difficulties and challenges due to the Covid-19 pandemic. The closure and movement prevention policies adopted by governments in many countries have greatly affected SMEs, paralyzing their

26. N. Blancher, *Financial Inclusion of Small and Medium-Sized Enterprises in the Middle East and Central Asia*, p. 29.

27. IMF, *World economic outlook update. Gloomy and more uncertain*, 2022, p. 1.

28. Ivi, p. 6, which states how “The risk of recession is particularly prominent in 2023, when in several countries economic growth is expected to bottom out, household savings accumulated during the pandemic will have declined, and even small shocks could cause economies to stall” (p. 7). ISTAT cited these IMF forecasts in April 2022 (pp. 1-2), noting how the international economic slowdown characterized by strong inflationary pressures and changing economic policies continues; the IMF’s most recent forecasts have revised their estimates for world GDP growth (+3.6%, +6.1% in 2021) downward. World trade in goods by volume moderately increased in February (+0.3%, +0.5% in January); however, the outlook remains negative.

operations, weakening their financial position, and exposing them to financial risk (Omar *et al.*, 2020; Oyewale *et al.*, 2020)²⁹.

In terms of the business crisis caused by Covid-19, it has been observed that “the Covid-19 pandemic has increased insolvency risks, especially among SMEs, which are overrepresented in the hard-hit sector”. These risks have increased to the extent that “without government intervention, even firms that are viable a priori could end up being liquidated, particularly in sectors characterized by labor-intensive technologies, threatening both macroeconomic and social stability³⁰”.

The OECD report “The territorial impact of Covid-19: Managing the crisis across levels of government”, stresses that “Across the OECD, SMEs account for 99% of all businesses and between 50% and 60% of valued added. SMEs are particularly vulnerable during the crisis (OECD, 2020). In addition to SMEs, the self-employed represent a considerable share of total employment in several OECD countries. Amounting to slightly less than 15% on average, self-employment is particularly prevalent in Greece, Italy, and Turkey, where it exceeds 20% (OECD, 2020). The self-employed are often less protected by unemployment benefits compared with standards workers³¹”.

The report emphasizes that “many subnational governments also took early action to support their local economies by supporting SMEs, artisans, retailers, and self-employed affected by the crisis. Emergency measures taken by regional and local governments cover a wide range of areas, from financial support to core indirect support schemes³²”.

29. N.A. Adam, G. Alarifi, *Innovation practices for survival of small and medium enterprises (SMEs) in the Covid-19 times: the role of external support*, in *Journal of Innovation and Entrepreneurship*, 2021, pp. 1-2.

30. F.J. Diez, R. Duval, J. Fan, J. Garrido, S. Kalemli-Ozcan, C. Maggi, M. Martinez-Peria, N. Pierri, *Insolvency prospects among small and medium enterprises in advanced economies: assessment and policy options*, IMF Staff Discussion Note, 2021, p. 5, states how “under current IFM projections, the note finds that the share of SMEs with negative equity, one definition of insolvency, may rise by 6% in 2022-21, threatening up to 1 in 10 SME jobs, or a number of jobs comparable to the total number of unemployed. This increase is similar to that seen in the five years after the global financial crisis, but it would occur over a much shorter period. In a downside scenario with extended lockdowns and persistently weaker demand, the share of insolvent SMEs would rise by 8%”.

31. OECD, *Tackling coronavirus (Covid-19): managing the crisis across levels of government*, 2020, p. 38.

32. Ivi, p. 39.

2. The World Bank

The WB, which aimed to make funds available to the countries most affected by the Second World War to aid in their reconstruction, devotes specific attention to SMEs.

The WB observed how SMEs “play a major role in most economies, particularly in developing countries. SMEs account for the majority of business worldwide and are important contributors to job creation and global economic development. They represent about 90% of businesses and more than 50% of employment worldwide, and formal SMEs contribute up to 40% of national income (GDP) in emerging economies. These numbers are significantly higher when informal SMEs are included”. In particular, “according to our estimates, 600 million jobs will be needed by 2030 to absorb the growing global workforce, making SME development a high priority for many governments around the world”³³.

Regarding developing countries, the World Bank pays significant attention to the fact that “in emerging markets, most formal jobs are generated by SMEs, which create 7 out of 10 jobs. However, access to finance is a key constraint to SME growth, and it is the second most cited obstacle facing SMEs to grow their business in emerging markets and developing countries”. In this context, “SMEs are less likely to be able to obtain loans than large firms: instead, they rely on internal funds, or cash from friends and family, to launch and initially run their enterprises. The International Finance Corporation estimates that 65 million firms, or 40% of formal MSMEs in developing countries, have an unmet financing need of 5.2 trillion US dollars (USD) every year, which is equivalent to 1.4 times the current level of the global MSMEs lending”³⁴.

Primarily, it is “East Asia and Pacific that accounts for the largest share (46%) of the global finance gap and is followed by Latin America and the Caribbean (23%) and Europe and Central Asia (15%). The gap volume varies considerably from region to region. The Latin American and Caribbean and the Middle East and North Africa regions have the highest proportion of the finance gap compared to potential demand, measured at 87% and 88%, respectively. About half of the formal SMEs do not have access to formal credit. The financing gap is even larger when micro and informal enterprises are taken into account”³⁵.

33. www.worldbank.org/en/topic/sme/finance.

34. The World Bank IBRRD IDA 2021, Formal MSME finance gap in developing countries: www.worldbank.org/en/topic/sme/finance.

35. The World Bank IBRRD IDA 2021, Formal MSME finance gap in developing countries: www.worldbank.org/en/topic/sme/finance.

To effectively support access to finance, the WB ensures a “holistic approach, combining advisory and lending services to clients to increase the contributions that SMEs can make to the economy, including underserved segments such as women-owned SMEs”. The WB commits to “advisory and policy support for SME finance, which mainly includes diagnostics, implementation support, global advocacy, and knowledge sharing of good practice”. Among these, the use of digital instruments “introducing innovation in SMEs such as e-lending platforms, use of alternative data for credit decisions, e-invoicing, e-factoring, and supply chain financing”³⁶ became essential during the pandemic³⁷.

Among the more significant studies put together by the WB is *Doing Business 2020*, which “shows that the developing economies are catching up with developed economies in doing business”^{38,39}.

Doing business 2004, *On understanding regulation* historically devoted specific attention to SMEs, emphasizing their reactivity to excessive regulations, while noting that the absence of any rules was not appropriate either.

In 2009, general tendency toward regulatory reform and simplification was revealed.

The 2010 *Doing Business* highlights the effects of the 2008 global financial crisis, observing important interventions to improve the regulatory frameworks; however, *Doing Business 2020* focuses on the creation of a legislative regulation for the new digital markets.

Indeed, “Regulation plays a central role in building the foundations of digital markets. It can provide the legal tools necessary for remote contracts, clarify the rights and obligations of the multiple actors involved in digital transactions and establish a framework that promotes consumer trust in digital markets, even when the consumer does not know the merchant, or the merchant is in a different country. However, regulation can also further segment digital trade, de facto restricting digital transactions within national boundaries, or allow for cross-border transactions with some partners to flourish while limiting others. This can be the intended result of regulatory measures that limit cross-border data flows, online purchases, or the undesired effect of regulatory differences across countries leading businesses to offer different goods and services across boundaries”⁴⁰.

36. *Ibidem*.

37. I. Adian, D. Doumbia, N. Gregory, A. Ragoussis, A. Reddy, J. Timmis, *Small and medium enterprises in the pandemic. Impact, responses and the role of development finance*, in *World Bank Group Policy Research Working Paper*, 2020.

38. The World Bank Group, *Doing business 2020*, p. 7.

39. *Ibidem*.

40. L. Daza Jaller, D.S. Gaillar, M. Molinuevo, *The regulation of digital trade: key policies and international trends*, The World Bank Group, 2020, p. 2, which instead underlines how today

In this case, “laws and regulations can foster or hinder digital trade. Regulations can play three different roles in digital markets. First, they can provide essential regulatory tools for remote transactions, such as electronic documents and signatures, as well as electronic payments. Second, they can improve the conditions for trust in digital markets by ensuring that consumers are protected and that their information is safe and remains private, increasing reliance and bringing new actors to digital transactions. A strong regulatory framework for these pillars can be associated with expanding digital trade. Third, regulations can introduce restrictions that hamper the conditions for digital markets. Restricting the types of goods and services that can be bought online, limiting or increasing costs for the transfer of data, which is necessary for transactions, or creating burdensome conditions for online marketplaces, platforms, and services providers, ultimately limits the offer of goods and services in digital markets”⁴¹.

Therefore, it should be pointed out that “regulation plays an essential role in bolstering digital markets by promoting trust [...]. Three sets of regulations are particularly relevant to promoting consumers’ trust in digital markets. An effective framework for online consumer protection helps consumers be better informed about the characteristics of the goods or services at hand and the terms of the transaction, promoting a greater understanding of the conditions of the transaction. Consumers must provide sensitive personal and financial details, and a strong data governance regime is essential to give individuals control over their information. Similarly, a cybersecurity framework further improves trust by ensuring that firms meet certain minimum technical standards in protecting their digital information and that illegal access to such data is duly prosecuted and, if needed, penalized”⁴².

The WB, in the World Development Report 2022, Finance for an equitable recovery, emphasized that “Covid-19 underscored the importance of strengthening financial resilience. The crisis disproportionately hit MSMEs and vulnerable groups, who typically have meager cash buffers. These vulnerable groups are overrepresented in sectors that suffered the most from the crisis. Job and income losses driven by lockdowns and mobility restrictions were deeply

“the regulation of digital markets is a patchwork of regulatory solution from different policy areas. Broadly speaking, the regulation of e-trade entails element of contract law, regarding documentation and signatures, financial law in what relates to e-payments, consumer protection, intellectual property, cybersecurity, personal privacy, and data protection” (pp. 2-3). What appears then is “A conducive regulatory framework in each of these policy areas is necessary for vibrant digital markets” (p. 3).

41. Ivi, p. 2.

42. Ivi, pp. 12-13.

felt by individuals and entrepreneurs, depleting already limited savings and assets. The WB predicted that poverty would worsen in low-income countries and that about 100 million people would fall into poverty in 2021⁷⁴³.

Therefore, it becomes important to access financial services, which are “essential for resilience and economic recovery. Digital payments, savings, credit, and insurance allow businesses and individuals to manage risk, smooth expenses, and invest. Evidence shows that households and businesses with access to such financial services are better able to withstand adverse financial shocks than those that do not⁷⁴⁴.”

In general, it emerges that “low-income households and MSMEs in emerging economies often rely on microfinance institutions (MFIs) instead of conventional banks for financial services. The microfinance sector consists of a diverse group of regulated and unregulated financial service providers⁷⁴⁵.”

In detail, “microfinance institutions are often the sole providers of financial services to vulnerable segments of a population. They play a critical role in local economies, household resilience, and women’s financial inclusion. One source suggests that up to 80% of MFI borrowers in emerging economies are female, and 65% are located in rural areas. MFIs rarely become large enough to threaten the stability of the financial system when they are in financial distress. But because many MSMEs and low-income households, including very poor, hard-to-reach populations, depend on MFIs as a source of credit and as a custodian of their financial assets, the safety and soundness of the microfinance sector are critical for this population⁷⁴⁶.”

MSMEs have been the firms hit hardest by the Covid-19 pandemic: “They are more vulnerable than debt-distressed large companies and less equipped to resort to the debt market or the legal system. It is, therefore, not surprising that they have shorter survival times; post-insolvency reforms due to Covid-19 should therefore address the specific needs of MSMEs to facilitate the recapitalization of viable but illiquid companies and the quick but less painful

43. The World Bank, *The World Development Report 2022*, p. 74.

44. *Ibidem*, p. 74, continues “a review of the literature suggests that MSMEs in OECD countries with access to credit are more likely to survive as employers and creators of economic value. And, as revealed in an analysis of the early impacts of Covid-19, a decline in output is less common among firms in low- and middle-income countries that had better access to finance before the pandemic (although firms with stronger fundamentals might have better access to credit). Financial inclusion also helps governments deliver services cheaper and faster. As the Covid-19 crisis erupted in 2019, countries with higher rates of financial inclusion were able to leverage that infrastructure to rapidly roll out government support, as evidenced by the experiences of China, Colombia, and India” (p. 75).

45. *Ivi*, p. 118.

46. *Ibidem*.

exit from the market of non-viable companies. This is particularly important in emerging economies where MSMEs account for a large proportion of total enterprises⁷⁴⁷.

Despite the important role of MSMEs in the economy, they struggle to access formal financial services: “About 130 million, or 41%, of low- and middle-income formal MSMEs countries faced credit constraints prior to the Covid-19 pandemic, and the finance gap of MSMEs (the difference between current supply and potential demand, which can potentially be addressed by financial institutions) has been estimated at 5 trillion USD. The question of finance from the informal enterprises was estimated at 2.8 trillion USD or 11% of the GDP of these countries. Policies to support the continuity of financial services to MSMEs and the informal sector and protect these clients through restructuring processes are essential to avoid delayed recovery. Although microfinance institutions (MFIs) are often small and may seem unimportant in balance sheet terms, they serve a segment of an economy that is macroeconomically significant. MFIs typically have detailed operational knowledge of local business conditions and the skills and abilities of individual entrepreneurs, which enables them to direct funds from recapitalized institutions to productive lending opportunities. Globally, the formal microfinance sector provides over 140 million low-income clients with credit and savings services⁷⁴⁸.

3. The Organisation for Economic Co-operation and Development

OECD is characterized today as an international organization for economic cooperation; inspired by the principles of economic liberalism, it focuses on the role of SMEs in the global context⁴⁹.

The OECD dedicates specific and historical attention to SMEs in The Bologna Charter on SMEs policy.

The policy recognizes “the increasing importance of SMEs in economic growth, job creation, regional and local development, and social cohesion, also through the role played by women and young entrepreneurs”. Additionally,

47. Ivi, p. 136.

48. Ivi, p. 149.

49. The OECD has also instituted a Centre for Entrepreneurship, SMEs, Regions and Cities (CFE), which “works with national and local governments, the business community, and other stakeholders to develop targeted support and evidence for the design, development and implementation of policies, as well as capacity building on entrepreneurship, SMEs, regions, rural and urban areas, local employment, tourism, culture, and multi-level governance”. See also OECD, Discover the Centre for entrepreneurship, SMEs, regions and cities, 2021, p. 2.

“entrepreneurship and a dynamic SME sector are important for restructuring economies and for combating poverty”, and “globalization, the acceleration of technological change, and innovation create opportunities for SMEs and also involve transition costs and new challenges”⁵⁰.

Moreover, “globalization should lead to higher living standards for all and its benefits should be accessible to all on an equitable basis”. Finally, “SME policies need to be tailored to the circumstances and priorities of individual countries and sectors while contributing to sustainable development and social progress”⁵¹.

The competitiveness of SMEs would benefit from “a regulatory environment which does not impose undue burdens on SMEs and is conducive to entrepreneurship, innovation, and growth through, inter alia, promoting good governance and greater accountability in public administration, pursuing a fair and transparent competition policy, implementing effective anti-corruption measures, and fostering the implementation of transparent, stable, and non-discriminatory tax regimes”. Furthermore, “education and human resource management policies that foster an innovative and entrepreneurial culture, including continuous training and lifelong learning, encourage mobility of human resources, and reduce skill disparities by improving the match between education and labor market demand” can help their competitiveness”⁵².

Other areas of focus include “effective access to financial services, particularly to seed, working, and development capital, including innovative financial instruments to reduce the risks and transaction costs of lending to SMEs, and an environment that supports the development and diffusion of new technologies for and by SMEs to take advantage of the knowledge-based economy”. Additionally, “strengthening public-private partnerships and political and social dialogue involving territorial and institutional actors as a tool for exchanging information, utilizing knowledge, and elaborating policy” can aid SMEs. Finally, SMEs can improve their competitiveness by “ensuring the cost-effectiveness of SME policies and their consistency with other national policies, as well as with existing international programs”⁵³.

To achieve this, it is necessary “to work together and within international organizations to improve the complementarity of bilateral and multilateral initiatives to promote global partnerships among SMEs and improve the

50. OECD, The Bologna Charter on SME policies, 2000, p. 4.

51. *Ibidem*.

52. *Ibidem*. Regarding anti-corruption measure, at a national level see M.O. Mantovani, *Il rafforzamento del contrasto alla corruzione*, in *Diritto penale e processo*, 2019, p. 608 ss.

53. OECD, The Bologna Charter on SME policies, 2000, p. 4.

availability of financial and non-financial instruments to promote the development of SMEs”⁵⁴.

More recently, the SME and Entrepreneurship Outlook 2019 observes, “digital technologies are evolving rapidly and combining in often unforeseeable ways, with large-scale effects on market structures and competitive conditions for SMEs”⁵⁵.

Digitalization is therefore “playing a major role in shaping market conditions and SME performance, whether through cheaper digital tools (ICT equipment) that provide scope for innovative firms to enter the market, the provision of digital services (which reduce the space between consumers and producers), or access to new (including international) market places via digital intermediation platforms, such as Amazon and Task rabbit, and other dedicated company websites”⁵⁶.

Moreover, “digitalization represents an important vehicle for SMEs to be ‘born global’ and opens new opportunities to enhance competitiveness through product or service innovations and an improved production process. Furthermore, big data and data analytics can enable a better understanding of the process within the firm, the needs of their clients and partners, and the overall business environment”⁵⁷.

The impact of digitalization on the financing sector has been significant for smaller companies, and fintech has been confirmed as a valuable avenue that “enabled innovation in financial services”.

Fintech offers “new opportunities for SMEs seeking finance. Digital platforms and blockchain technology, in particular, have the potential to revolutionize the financial industry”. Fintech “enables mobile banking, settling (international) payments and collecting and using alternative data sources for assessing SMEs creditworthiness, etc. This technological development is likely to have a high impact on financial inclusion, as they often drive transaction

54. *Ibidem*.

55. OECD, SME and entrepreneurship outlook 2019, p. 65, which underlines that “Shift in client demands and supply chain processes are exerting pressure to reshape business models to become more compatible with the digital era of continuous connection and instantaneous global reach. The impact of advanced digital technologies has also transformed and disrupted many sectors traditionally dominated by SMEs, notably transportation (e.g., Uber), restaurants (Deliveroo), real estate (via a whole range of online platforms), or travel and accommodation (Expedia, Booking.com, Airbnb)”.

56. Ivi, p. 65.

57. Ivi, p. 66, which states that “Digitalization has also transformed the possibilities of scaling up, and different form of business growth are emerging, with some companies to able to achieve significant scale, market share and high productivity without affording large investment in tangible assets. ‘Lean startups’ are emerging that leverage the Internet to lower fixed costs and outsource many aspects of the business to stay agile and responsive to the effect market”.

costs down, making it profitable for financial institutions to serve segments of the SME population that were previously left aside, such as very small and informal businesses or firms operating in remote and peripheral areas”⁵⁸.

Notably, blockchain technology⁵⁹ “allows transparency in transactions, including the transfer of value, assets, and ownership, and a full disintermediation as the transfer take place within computer networks on the basis of a consensus among peers. Applications for SME finance include syndicated loans (where a group of lenders work together to offer a loan to a single borrower, coordinating through blockchain and smart contracts), supply chain financing (with smart contracts enabling all parties in a supply chain finance to act on a single shared ledger, with an unprecedented level of trust and efficiency, especially in cross-border value chains), or tokenized loans with digital assets posed as collateral (also through smart contracts)”⁶⁰.

The revolutionary impact of the Internet on regulations has highlighted the need for regulators to construct a legal framework that assures all business enterprises, particularly smaller ones, can compete on a level playing field.

This framework includes “regulation in product and labor markets, taxation, competition, insolvency entrepreneurship, and SME development at all stages of the business cycle, including entry, investment, transfer, and exit”⁶¹.

There is no doubt that “an effective regulatory environment, which provides clear and universal rules of the game, is essential for promoting risk-

58. Ivi, p. 189.

59. See R. De Caria, *Definitions of smart contracts. Between law and code*, in L.A. Di Matteo, M. Cannarsa, C. Poncibò (eds.), *The Cambridge handbook of smart contracts, blockchain technology and digital platforms*, Cambridge University Press, 2019, p. 19 ss.; R. De Caria, *Blockchain and smart contracts: legal issues and regulatory responses between public and private economic law*, in *The Italian Law Journal*, 2020, p. 363 ss.; R. De Caria, *Blockchain and sovereignty*, in O. Pollicino, G. De Gregorio (eds.), *Blockchain and public law. Global challenges in the era of decentralization*, Cheltenham, UK, 2021, p. 41 ss.; G. Lemme, *Blockchain, smart contracts, privacy, o del nuovo manifestarsi della volontà contrattuale*, in E. Tosi (a cura di), *Privacy digitale. Riservatezza e protezione dei dati personali tra GDPR e nuovo Codice Privacy*, Milano, 2019, p. 293 ss.; G. Lemme, *Gli “smart contracts” e le tre leggi della robotica*, in *Analisi giuridica dell’economia*, 2019, p. 129 ss.; G. Lemme, *La transizione giuridica. La crisi del diritto di fronte alla sfida tecnologica*, Torino, 2023.

60. OECD, *SME and entrepreneurship outlook 2019*, p. 190, which states how “Initial coin offering (ICOs) are the main financing models introduced within blockchain technology and can be attractive for startups aiming to raise funds with very limited restrictions and low regulation scrutiny. ICOs are public financing calls following which token are issue and sold against crypto currencies or fiat currencies. Tokens issued through ICOs do not usually grant voting rights or decision-making power but can also be used to access company’s services or products”.

61. Ivi, p. 94. Taxation is one of the major problems for enterprises, which was worsened by the Covid pandemic. At a national level see F. Tundo, *Proroga incondizionata dei termini per gli accertamenti fiscali per fronteggiare l'emergenza sanitaria*, in *Il Fisco*, 2020, p. 1507 ss.

taking, incentivizing business investment, lowering informality and reducing corruption”. Such conditions are critical “for startups and SMEs since the proportion of resources that they divert to administrative functions is usually greater than for large firms; as a consequence, unnecessary regulatory burdens affect them disproportionately”⁶².

In this context, it becomes essential to have smart regulations aimed at “improving the quality and the outcomes of the regulatory process, simplifying administrative procedures, and cutting red tape at the core of pro-growth reforms in many countries. Governments have been promoting smart regulation by integrating SME-related considerations upstream in regulatory policymaking, encouraging broader stakeholders’ consultation, and reinforcing regulatory impact analysis”⁶³.

Countries have progressively formalized some guiding principles to realize a specific smart regulation, including “transparency, accountability, and participation. Efforts are placed on strengthening public sector integrity and facilitating collaborative approaches with businesses and citizens, as a response to declined confidence in national governments”⁶⁴.

Furthermore, “Great data availability also enables governments to better adapt public sector operations to end users’ needs and preferences. Behavioral insights are being applied to better integrate a user perspective in policy delivery. Data analytics is also transforming the relationship between tax administration and taxpayers and improving tax compliance conditions. Reforms hinge on a comprehensive infrastructure for information exchange across government bodies, individuals, and businesses”⁶⁵.

Despite global efforts to improve legal regulation and build smart regulations, especially for SMEs, and “despite significant progress in adoption, challenges remain for ensuring even quality in regulatory impact analysis (RIA) processes and outcomes and increasing its effectiveness in small business regulation. Barriers include the lack of SME-related data and shared methodologies within administrations, as well as limited resources and analytical capability in regulatory bodies. RIA is, in fact, a time-consuming and resource-intensive process, which calls for prioritization. A general tendency is observed to adopt a natural approach and use RIA as a legitimization tool rather than as an information instrument and a learning process in support of decision-making”⁶⁶.

62. Ivi, p. 94.

63. *Ibidem*, which states that “However, ex post evaluation system remains underdeveloped”.

64. *Ibidem*.

65. *Ibidem*.

66. Ivi, p. 97, where it is stated that “Enhancing the application of RIA in the policy process requires significant investment to trigger a change in the administration and strengthen the

Other significant points can be found in a report entitled *Strengthening SMEs and Entrepreneurship for Productivity and Inclusive Growth*.

In the report, the OECD discusses the need to create an adequate and innovative model for small businesses in terms of legislative regulation, “there is no one-size-fits-all model”⁶⁷.

Among the key elements⁶⁸, it indicates “the use of digital technologies to reduce administrative burdens and facilitate collaborative relationships with businesses and citizens”⁶⁹, with greater use of “e-government services [...] such as through the creation of digital “one-stop shops, i.e., single entry points for government services. In this context, the use of digital technologies holds the potential to further streamline procedures for SMEs in particular”⁷⁰.

In 2020, the OECD published the *Evolution and Trends in SME Finance policies since the Global Financial Crisis* report, analyzing the most significant changes “in the SME finance environment since the financial crisis, along with the principal policy and regulatory responses”⁷¹.

The report mentions that “policy developments are increasingly shaped by

economic analysis of regulatory proposals in contexts often dominated by legal experts. It also demands political commitment, support from stakeholders, and consistency across the levels of governments”.

67. OECD, *Strengthening SMEs and entrepreneurship for productivity and inclusive growth*, in OECD 2018 Ministerial Conference on SMES, 2019, p. 91.

68. *Ibidem*, which includes some of the key elements necessary “to enhance regulatory conditions for SMEs” also “simplification of regulations and administrative procedures, regulatory impact assessment, reforms to tax administration and bankruptcy procedures, including to promote a second chance for honest entrepreneurs, improved availability and provision of information”. The same report refers to Recommendations of the OECD Council on regulatory policy and governance, 2012, indicating some of the key areas to hold in consideration when defining specific political interventions for smaller businesses. These areas include “Improving the efficiency of bankruptcy procedures and fostering a second chance for honest entrepreneurs, facilitating tax compliance, cutting red tape for businesses, strengthening public sector integrity and transparency and cutting RIA to enhance the effectiveness of regulation and assess its implications for SMEs” (p. 96). See R. Perrone Capano, *L'evoluzione sul rapporto tra evasione ed economia sommersa, dall'abbandono della lira fino alla crisi globale, economica e sociale con epicentro in Europa*, in *Innovazione e Diritto*, 2021.

69. OECD, *Strengthening SMEs and entrepreneurship for productivity and inclusive growth*, in OECD 2018 Ministerial Conference on SMES, 2019, p. 91.

70. Ivi, p. 93.

71. OECD, *Evolution and trends in SME finance policies since the global financial crisis*, 2020, p. 5. The impact of the Covid-19 pandemic is analyzed at a general economic level in OECD, *Tackling coronavirus (Covid-19). Contributing to a global effort, “evaluating the initial impact of Covid-19 containment measures on economic activity”*, June 2020. See N. Moy, M. Antonini, M. Kyhlstedt, G. Fiorentini, F. Paolucci, *Standardising policy and technology responses aftermath of a pandemic: a comparative and conceptual framework*, in *Health Research Policy and Systems*, 2023, p. 1 ss.

megatrends such as globalization, digitalization, and aging. Digitalization offers new opportunities and challenges for policymakers and SMEs seeking finance. Fintech, defined as technology-enabled innovation in financial services, is becoming increasingly important in easing SMEs' access to finance. It is also ensuring financial inclusion for the same segment of the SME population that are traditionally served or unserved by financial institutions and markets⁷².

The new digital technologies represent a genuine opportunity for smaller businesses; in particular, “using technologies such as digital ID verification, distributed ledger technologies, big data, and marketplace lending, new suppliers are offering an array of innovative services with the potential to revolutionize SME finance markets”⁷³.

Therefore, “Mobile banking, (international) mobile payments, and the use of alternative data for credit risk assessment can significantly reduce information asymmetries and transaction costs, tackling structural barriers SMEs face when accessing finance”. In other words, “fintech will likely become a more central feature in the range of SME financing options in the coming years”⁷⁴.

In 2021, the OECD published *The Digital Transformation of SMEs*. The study shows how “The digitalization of businesses has continued apace in recent years” and that “all sectors and firms of all sizes are increasingly equipping their staff with computer and Internet access, although small firms do so more slowly, and some sectors do so more quickly (e.g., construction, logistic, and real trade)”⁷⁵.

The gap widens when “technologies become more sophisticated or mass matters for implementation”, such that “micro-firms go under the radar, i.e., about 90% of the business population in OECD countries are not covered by international statistics on digital uptake by businesses”⁷⁶.

Given this, “governments implement a mix of policy approaches from technology support programs to skill development, to alternative sources of

72. Ivi, p. 7.

73. *Ibidem*.

74. *Ibidem*. On this point, see also OECD, *Financing SMEs and entrepreneurs 2020: an OECD Scoreboard, 2020*, and OECD, *The impact of Covid-19. A special edition of the OECD Financing SMES and entrepreneur's scoreboard, 2020*, p. 7, which highlights how “the financing environment was generally favorable in the run-up to the pandemic, despite sluggish growth in SME lending as SMEs increasingly turned to internal finance and alternative external instruments for their financing needs. However, the Covid-19 crisis hit SME revenues and profitability extremely hard creating acute liquidity shortage for many firms”. On the same issue, see also M. Auboin, *Trade finance, gaps and the C-19 pandemic: a review of events and policy and policy responses to date*, World Trade Organization Staff Working Paper, 2021, p. 2.

75. OECD, *Studies on SMEs and entrepreneurship: the digital transformation, 2021*, p. 16.

76. *Ibidem*.

finance and fintech, to improved SME capacity to manage and protect their data, or to adopt sound digital security practices, to promote e-government as a lever for business adoption, to develop high-quality infrastructure and networking platforms and facilities”⁷⁷.

Furthermore, “The Covid-19 outbreak is providing a striking example of the role SMEs play in ensuring resilience and sustainability and how digitalization can help them improve the process and offer”⁷⁸.

In particular, “many SMEs have been experimenting with innovative forms of production and sales, often leveraging digitalization to develop working methods to help them cope with containment and social distancing measures (OECD 2020). Business surveys conducted worldwide since the beginning of the Covid-19 pandemic converge in highlighting the rapid uptake of teleworking and digital sales channels among SMEs, signaling an acceleration in their digital transformation”⁷⁹.

More specifically, “Digitalization can also help SMEs integrate into global markets, as it reduces the costs associated with transport and border operations, increases the tradability of many services (where SMEs are the majority), and reduces some hidden costs that fragmented global value chain (GVCs) raise (additional management, logistics, and operations)”⁸⁰.

The digitalization process creates “conditions under which SMEs access strategic resources. It creates a range of innovative financial services for businesses that traditionally face greater difficulties in accessing finance. From peer-to-peer lending to alternative risk assessment tools to initial coin offering (ICO) issuing crypto assets, blended financing models are on the rise. Fintech is becoming increasingly central in the SME finance landscape, and established market players are increasingly adopting fintech instruments. Digitalization also eases SMEs’ access to skills through job recruitment platforms, outsourcing, and online task hiring, or by connecting them with knowledge partners”⁸¹.

Together with the rapid digitalization of the market, the parallel attempt to transform public administration requires that “E-government and online

77. Ivi, p. 16.

78. Ivi, p. 18. The same study also says, “The business survey conducted in the course of 2020 worldwide documents the increase in the uptake of digital technologies and online sales by SMEs from May 2020 onwards. The survey shows that at the start of the Covid-19 pandemic, up to 70% of SMEs are making more use of digital technologies, although substantial differences exist between countries. However, the difference between SMEs, particularly small firms, and large firms continues to be significant with the uptake of digital technologies by SMEs being only half of that by larger firms” (p. 34).

79. Ivi, p. 18.

80. Ivi, p. 19.

81. *Ibidem*.

platforms facilitate consultations and public service delivery to SMEs. Digital applications are already spreading across a broad range of areas, from business development services to license systems, to tax compliance, to courts”.

In this context, “greater data availability, combined with behavioral insights, is enabling governments to better adapt their services to user preferences and creates room for policy experimentation (e.g., tax compliance by design), improving overall SME policy efficiency”⁸².

The OECD study mentions that the “digitalization of public services can bring several benefits to small businesses. It can help reduce bureaucratic complexity and transaction costs in interacting with public administration, which tend to divert a relatively larger share of their resources to administrative functions. It can increase data availability on end users’ usage and preferences, enable a more user-centric approach in policy delivery, and enhance the level playing field for government to SME interaction. It can also provide SMEs with incentives to further technology adoption”⁸³.

In this context, “E-government applications are already spreading across a broad range of areas, including business development services, license systems, tax declarations, business registrations, export assistance, public procurement of courts, etc. There is an increasing trend to link different portals so that businesses do not have to provide the same information for different needs (the ‘only once’ principle). Typically, single digital portals or digital ‘one-stop shops’ serve as single entry points for accessing e-government services and reducing redundancy in public administration requests”⁸⁴.

Furthermore, in SME digitalization to “Build Back Better”, the OECD specifies, “digitalization of SMEs is crucial in building inclusive and resilient economies and societies. Ensuring the uptake of digital technologies by all SMEs and entrepreneurs is central to fully unlocking the potential of the digital revolution at large”⁸⁵.

However, “many SMEs risk missing the benefits digitalization can offer. At the firm level, digital gaps are strongly associated with gaps in productivity, scaling up, innovation, and growth. These gaps contribute to inequalities among firms, and, in turn, people and places, with concerns that the benefits of digitalization could accrue mainly to early adopters”⁸⁶.

In this way, public policies “play a focal role in enabling SMEs to adapt their

82. *Ibidem*.

83. Ivi, p. 46.

84. *Ibidem*.

85. OECD, SME digitalization to “build back better”. Digital for SMEs (D4SME) Policy Paper, 2021, p. 11.

86. *Ibidem*.

business models and practices to the digital economy. Even before the pandemic, SME digitalization was high on the policy agenda across OECD countries and beyond. This focus has only intensified, with governments introducing recovery tools and legislations aimed at enabling SME digitalization, as well as newly designed instruments and others that build upon pre-pandemic policies⁸⁷.

An analysis conducted by the OECD indicates that one may find “a large mix of policy approaches targeting SME digitalization and, in some areas, diverging viewpoints on how to unleash their digital potential. The heterogeneity of the SME population and the diversity of their business ecosystems add to the complexity of designing effective policy. Some countries seek mainstream SME policy considerations in other policy agendas, and others target SMEs, with instruments often tailored to specific places or sectors. In some countries, policy strategies focus on financial support, while others focus on consultancy and non-financial support or a mixture of the two approaches. Similarly, there is a growing focus on the diffusion of targeted technologies such as artificial intelligence or blockchains, with tailor-made instruments for specific digital tools⁸⁸”.

The OECD Scoreboard “Financing SMEs and Entrepreneurs 2022” states that at the global level, “the pandemic significantly disrupted world trade, which was already under considerable strain over the previous decade”.

In particular, “SMEs were impacted strongly by trade disruptions along the value chain. The biggest disruption occurred in Q2 of 2020, with strict lockdown measures in many economies, but frictions have persisted through 2020 e 2021. In China, exports fell about 21% in February compared to the same period in 2019 before beginning to recover (International Trade Center, 2020). In the last quarter of 2020, 69% of SMEs in Europe reported having difficulties in importing materials, goods, and services, and 46% reported specifically facing disruption to supply chains, which led to shortages of food. SMEs also incurred additional financial costs due to these disruptions, with 26% reporting paying higher and 39% facing late payments compared to the same period in 2019 (European Commission, 2021)⁸⁹”.

Furthermore, regarding access to funding, “The Covid-19 crisis and related policy interventions had a significant impact on the dynamics of lending to SMEs in 2020”. At the beginning of the crisis, “SME liquidity needs soared due to significant revenue shortfalls. While some of these shortfalls were offset by lower expenses due to temporary closures, as well as relief measures such as tax deferrals, wage subsidies, and moratoria on debt repayments, the remaining

87. *Ibidem*.

88. Ivi, p. 39.

89. OECD, OECD scoreboard “Financing SMEs and entrepreneurs”, 2022, p. 2.

gaps had to be filled with new financing. Moreover, many SMEs sought to build precautionary liquidity buffers considering the uncertain evolution of the pandemic”⁹⁰.

In 2022, “SMEs in the same sector are encountering challenges as a result of increased volatility and price increases in the commodity market. Russia and Ukraine together account for about 30% of global exports of wheat, 20% of corn, mineral fertilizers, and natural gas, and 11% of oil (OECD, 2022). SMEs that rely on these inputs, particularly European SMEs, are likely to be affected”⁹¹.

In these economically and socially challenging times, digital finance instruments continue to play an important role: “Online alternative finance is a means of soliciting funds from the public for a project/firm through an intermediate platform, usually through the Internet. The online alternative finance ecosystem comprises debt, equity, and non-investment models that allow entities to raise funds through an online digital marketplace. The debt-based model covers P2P/marketplace lending and includes secured and unsecured loans, bonds, and debtor notes. Equity-based models, including equity-based crowdfunding, relate to activities where businesses, particularly startups, raise capital by issuing unlisted shares or securities. Non-investment-based models in which individuals of firms raise capital, but they are not obliged to provide a monetary return to the individuals or institutions that funded the project. They include reward-based and donation-based crowdfunding (Cambridge Centre for Alternative Finance, 2021)”⁹².

Further, we need to reiterate that data can play an important role in improving the economic activity of SMEs, primarily if they are supported by specific policies aimed at “helping SMEs turn data into economic value to scale up business activities and grow. With data emerging as a key driver of firm performance and potentially enabling a broader deployment of more sustainable energy and resource-efficient business models, there is a need to better understand the extent to which and how governments act for improving SME data governance”⁹³.

90. Ivi, p. 3.

91. Ivi, pp. 2-3, which states “Supply chain disruptions persisted in 2021 and early 2022” and in fact “the sharp rise in the demand for goods, in combination with the re-introduction of pandemic restrictions including China’s zero Covid policy has congested the world busiest ports and exhausted shipping capacity. With important ports closing and the restriction on movement causing significant shortage of workers and drivers, in October 2021, the global delivery time index registered the worst month on record. This has impacted inventories, causing shortages and affecting manufacturers worldwide (Reuters, 2022)”.

92. Ivi, p. 17.

93. Ivi, p. 135.

To facilitate the transition and resilience of SMEs and entrepreneurs, the OECD, in the Recommendation of the Council on SME and Entrepreneurship Policy of June 10, 2022, advocates that adherents promote “and implement effective, efficient, and coherent policies for SME and entrepreneurship to foster their contribution to inclusive and sustainable growth and for the benefit of all”⁹⁴.

For this purpose, adherents should “put in place cross-cutting and coherent approaches to SME and entrepreneurship policy design and implementation by coordinating and aligning SME and entrepreneurship policy across government entities and levels through effective governance mechanisms and place based-approaches, in line with each country’s institutional setting, circumstances, and needs”. Such policies can aim at “ensuring that implications for SMEs and entrepreneurs are considered across the diverse policy areas that influence their prospects and outcomes to enhance policy synergies, address potential trade-offs and reduce administrative burdens, including through increased attention to their specificities and circumstances in policy and regulatory design, SME tests and evaluations, consultation mechanisms, streamlined processes, and user-centric approaches in implementation”⁹⁵.

In terms of digitalization, the OECD Recommendation highlights how to strengthen and help the transition processes of SMEs, it is necessary to “support the adoption of digital technologies, services, and data by all SMEs and entrepreneurs in line with their needs, digital maturity, and aspirations by enhancing access to digital infrastructure; strengthening digital skills, data literacy and management of digital security risk; and ensuring open and well-functioning markets for digital goods and services”⁹⁶.

Furthermore, “encouraging and enabling SMEs and entrepreneurs to transition to sustainable business models, practices and technologies, and to drive green innovations, taking into account their specificities and needs in environmental policies; fostering their access to resources, including sustainable finance; and supporting their adoption of circular economy strategies”⁹⁷.

94. OECD, Recommendation of the Council of SME and Entrepreneurial Policy 10 June 2022, p. 2, introduces, “the drastically changing environment in which SMEs and entrepreneurs operate through digitalization, climate change and internationalization, and the need for policies to address these”, and recognizes “the importance of SMEs and entrepreneurs for economic growth, job creation, regional and local development, sustainability and social cohesion”. Furthermore, “SME and entrepreneurship policies have a broad and varied scope, ranging from measures specifically targeted to SMEs to strengthening framework conditions and supporting the wider business community, and involve a variety of actors across governments at central and subnational level” (pp. 2-3).

95. Ivi, p. 2.

96. *Ibidem*, p. 2.

97. Ivi, p. 2.

4. The World Trade Organization

The WTO⁹⁸ devotes specific attention to the most pertinent issues affecting smaller businesses, highlighting that because SMEs participate “less in international trade compared to large firms, they are typically less productive and face size-related disadvantages”. Additionally, “the mobilization of investment in ICT infrastructure, both public and private, as well as the creation of a regulatory environment that provides for sound competition in the telecommunication sector”⁹⁹ is vital for SMEs.

The significant proposals of the WTO include the Work Program for Aid for Trade (A4T), the Trade Dialogue, the Small Business Champion, and the institution of a specific Informal Working Group dedicated to SMEs¹⁰⁰ in 2017.

Concerning this, the Annual Report 2020 specifies that “The group, whose members account for around 80% of world exports, held four meetings, in February, June, October, and November, and a drafting session in December to discuss proposals for a declaration on MSMEs at MC12. The objective is a declaration that includes recommendations, decisions, calls to action, and a work program. The proposals submitted include the development of a new online platform with links to useful, practical tools for MSMEs (online courses and relevant websites) and policymakers (useful studies and information on good practices)”¹⁰¹.

98. Established by the Marrakesh Agreement on 15 April 1994, the WTO is the Forum for multilateral trade negotiations between States regarding trade agreements they have reached, and one of its purposes is to ensure the enforcement of regulatory law and to remove obstacles to trade. See also E. Baroncini, *Unione Europea e rule of law nella governance dell'economia globale: l'approccio al contenzioso per il libero scambio*, in *Beni e valori comuni nelle dimensioni internazionale sovranazionale*, Napoli, 2021, p. 237 ss.

99. R. Lanz, K. Lundquist, G. Mansio, A. Maurer, R. Teh, *E-commerce and developing country*. SME participation in global value chains, OECD Staff Working Paper, 2018, p. 2, highlight that “ICT is now considered a pre-requisite for joining most GCVs. However, a recent study by the World Bank claims that the most important technological requirements is still basic access to the Internet. No matter the Internet’s functionality, regardless of lacking features such as broadband connection and e-commerce platform, e-commerce can develop if the Internet is present”.

100. World Trade Organization, Joint ministerial statement. Declaration on the establishment of a WTO informal work programme for MSMEs, 2017, in Ministerial Conference Eleventh Session Buenos Aires.

101. World Trade Organization, Annual Report 2020, p. 51. Also of interest is the WTO Information Note, E-commerce, trade and the Covid pandemic, 2020, p. 4, which states “Governments have adopted new measures and the private sector has also acted to respond to ensure that e-commerce can help to alleviate some of the challenges faced in combating the virus. These include increasing network capacity, offering expanding faced data services at little or no cost, lowering or scrapping transaction costs on digital payments and mobile

The Informal Working Group on MSMEs (arranged by the WTO in December 2017 to “address obstacles to MSME participation in international trade”) instituted a specific database in 2019.

The database contains information regarding SMEs in trade agreements and, in 2020, adopted initiatives aimed at supporting SMEs that wish to expand their activities internationally. Additionally, relating to our study, the Global Trade Helpdesk (which was promoted “jointly by the International Trade Center (ICT), the UN Conference on development and trade, and the WTO”¹⁰²), which consists of an online platform aimed at creating a bank of business information related to SMEs.

The relevance of new technological and digital tools, which “open a range of new opportunities for small firms to play a more active role in GVCs”¹⁰³, is considered in the 2019 Global Value Chain Development Report, Technological Innovation, Supply Chain Trade, and Workers in a Globalized World.

The relevance of the problems related to the role of SMEs within the WTO is analyzed in a 2020 analysis, which indicates that due to the pandemic, “MSMEs are particularly exposed to the Covid-19 pandemic’s economic impact because of limited financial resources and borrowing capacity, and because of their disproportionate presence in the economic sector affected by social distancing measures and transport disruption. MSMEs are particularly exposed to the trade restrictions on agricultural products”¹⁰⁴.

Smaller businesses “are among those facing some of the greatest economic difficulties from Covid-19” and “are disproportionately affected by the Covid-19

money transfer, improving delivery services and other logistics, using digital tools to enforce measures and disseminate information, promoting telehealth services, and leveraging ICT for surveillance”.

102. Ivi, p. 51. See also the WTO Information Note “The economic impact of Covid-19 on women in vulnerable sectors and economies”, 2020, p. 1, which specifies that “A large share of firms owned or managed by women are MSMEs and lower levels of financial resources and limited access to public funds are placing the survival of such businesses at greater risks”. See also the WTO Staff working paper Trade finance, gaps, and the Covid-19 pandemic: a review of events and policy responses to date, 2021, p. 19, which emphasizes that “Central Banks of many countries in the world, including in the main financial centers, had extended exceptional liquidity facilities to banks, to ensure the liquidity of the financial system. Governments also activated many schemes and distressed funds for SMEs facing challenges in repaying loans and dealing with debts during Covid-19 period, including arrangements delaying repayments of loans and interest, extending loans terms, and supporting bank to supply of trade facilities in favor of SMEs”.

103. WTO, IDE-JETRO, OECD, UIBE, Global Value Chain Development Report, Technological Innovation, Supply Chain Trade, and Workers in a Globalized World, 2019, p. 121.

104. World Trade Organization, Helping MSMEs navigate the Covid-19 crisis, 2020, p. 1.

pandemic because of their prevalence in the economic sector most affected by demand shock caused by the pandemic. These sectors include accommodation and food service, the cultural and creative sector, and wholesale and retail services (OECD, 2020). Data for OECD and some non-OECD economies show that MSMEs export more than large firms in these sectors, leading to a dramatic loss of demand and revenue in these areas for both domestic and trade activities”¹⁰⁵.

Nonetheless, “MSMEs are also greatly exposed to the economic downturn resulting from Covid-19 because of their size. For example, they typically have relatively low cash reserves and thus only a small cushion to weather economic shock [...]. Moreover, MSMEs generally have inventories and suppliers’ networks. Sourcing from new suppliers or absorbing price increases is more challenging for a small firm with limited supply options and capital, meaning that supply chain disruptions can impact MSMEs faster and harder than large firms”¹⁰⁶.

In this regard, we should note that “MSMEs have limited resources with which to navigate the current rapid changes in government policies and to deal with application requirements to access Covid-19 business resources. The current crisis exacerbates these challenges. New trade measures are being taken by governments every day in response to Covid-19. If the different actors engaged in the supply chain are unaware of these new requirements, they can struggle to adapt to the new conditions”¹⁰⁷.

In response to the pandemic crisis, smaller companies were subject to initial intervention measures by their respective states, whereby “supporting MSMEs is vital for preserving jobs and productivity”. In fact, “governments have introduced a wide range of urgent stimulus and backstop measures for businesses, especially for MSMEs. These measures, which are often time-limited, mostly include direct and indirect liquidity support measures meant to address the cash flow issues MSMEs are currently experiencing”: these measures specifically regarded “liquidity support, particularly state loans, credit guarantees, wage subsidies, and the deferring of tax payments, such as value-added/goods and services taxes”¹⁰⁸.

During the pandemic, the Informal Working Group on MSMEs put forward some proposals, including the development of an online platform “with links to practical tools for both MSMEs (such as online courses and market analysis

105. Ivi, p. 2.

106. Ivi, p. 4.

107. *Ibidem*.

108. *Ibidem*.

tools) and policymakers (including useful studies and information on good practice)¹⁰⁹.

From the point of view of trade finance, the WTO has focused on trade finance shortages.

Particular attention was given to measures that support “the trade finance facilitation programs of multilateral development banks by way of advocacy and mobilization” and “reduce the knowledge gap regarding trade finance products and regulation through on-site training or e-learning”, as well as “increase dialogue with trade finance regulators”¹¹⁰.

The Informal Working Group on MSMEs published the Declaration on micro, small, and medium-sized enterprises¹¹¹ recognized in 2021. The study recognized that “promoting the participation of MSMEs in international trade is an important issue in the WTO agenda, all the more considering the significant negative impact that the Covid-19 pandemic has had on MSMEs, as well as the contribution that the WTO can make to support the global recovery”¹¹².

According to the WTO, “MSMEs amount to 95% of business globally and 60% of global employment”¹¹³.

However, they are underrepresented because “the international legal environment insufficiently takes their needs and constraints into account, particularly in terms of trade financing, cross-border payments, and trade facilitation.

Trade finance is essential to allow firms, particularly MSMEs, to diversify import and export markets, but trade finance tends to be increasingly difficult to obtain in middle- and low-income countries. During the 2008-2009 global financial crisis, which significantly impacted the availability of trade finance, the WTO, among other contributions, engaged with regulators to ensure that improved access to trade finance was reflected in the new financial stability rules”¹¹⁴.

In this production context, the issue of defining a new legal regulation in the digital age becomes increasingly important because “a growing number

109. Ivi, p. 6. On this point, see also L. Tajoli, *Quadro del commercio mondiale nel 2020*, in *Osservatorio di politica internazionale*, April 2020, p. 27. Regarding international contracts see N. Soldati, F. Marrella, *Arbitration, Contracts and International Trade*, in *Studi in onore di Giorgio Bernini*, Milano, 2021, p. 683 ss.

110. World Trade Organization, *Helping MSMEs navigate the Covid-19 crisis*, p. 7.

111. World Trade Organization, *Informal working group on MSMEs*, 2021.

112. Ivi, p. 1.

113. World Trade Organization, *Economic resilience and trade*, World Trade Report 2021, 2021, p. 138.

114. *Ibidem*.

of governments have adopted policies aimed at boosting growth through innovation and technological upgrading. The domestic economic fallout linked to the Covid-19 pandemic is leading countries to strengthen these policies”¹¹⁵.

However, this is particularly urgent for smaller companies, which are operating in an entirely new economic and production context, as we will illustrate in the remainder of this study.

Regarding this point, the WTO Chairs Program, entitled *Adapting to the digital trade era: challenges and opportunities* (2021), is notable.

The program examines the legal regulations governing digital trade at the international level, highlighting that “international digital trade presents a challenge due to the lack of clearly defined global rules, meaning that there is no coherent set of guidelines for countries to ensure the free flow of digital trade internationally”. Furthermore, “the last major round of negotiations of the WTO to have been completed, the Uruguay round, predated the rise of digital trade and, since then, no real progress has been made to update the rule”¹¹⁶.

115. World Trade Organization, *Government policies to promote innovation in the digital age*, 2020, p. 6.

116. The World Trade Organization, *Chairs Program, Adapting to the digital trade era: challenges and opportunities*, 2021, p. 217.

2. SMEs and new industrial policies in the digital single market

SUMMARY: 1. Legal regulation of the European industrial sector: Origins and evolution – 2. Legal regulation of SMEs in Europe; small and medium-sized businesses and the Small Business Acts: The principle of “Think Small First”, which is the key step toward the legal recognition of the importance of small businesses for the European economy – 3. A new Industrial Strategy for Europe: The Digital Single Market (and the Review); challenges and digital opportunities for small businesses – 4. A new orthogonal axis for the European industry. The Twin Transition and An SME Strategy for a Sustainable and Digital Europe.

1. Legal regulation of the European industrial sector: Origins and evolution

The current geopolitical situation and post-pandemic context have accelerated and necessitated a profound rethinking of the industrial policies that have characterized European-level industries.

The European Commission has highlighted limits and potential in its Communication n. 62 on February 1, 2023, A Green Deal Industrial Plan for the Net Zero Age¹.

The Communication placed industrial innovation and clean technologies aimed at zero emissions at the fore of economic development, which we analyze further in this study.

To understand the scope of this plan, it helps to retrace the origin of industrial legislative regulation, which has had deep roots in Europe since the Second World War.

At the time, Europe played a marginal role concerning the new industrial powers, so much so that Churchill noted in his diaries how “old Europe” had

1. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, A Green Deal Industrial Plan for the Net-Zero Age, 1 February 2023, n. 62.

ended at the Yalta Conference in 1945 when the new superpowers were deciding on how to divide the world².

In turn, the individual member states were also, at the time, experiencing political, historical, and social tensions³ that inevitably impacted the legal regulation of the industrial sector.

This impact mainly involved large industries, which were considered the only possible organizational form where capital, science, and organizations could profitably come together.

The relevance of difference in size between enterprises is still studied today in economic science, highlighting the strong contrast between large and small enterprises.

This contrast has been present since the 19th century and became more evident with the rise of Fordism and the technological developments following the Second World War.

In this context, a “large enterprise” appears as the location and, simultaneously, the most rational organizational solution to production problems. Conversely, a production system characterized by medium and small enterprises indicates a country’s backwardness⁴.

In this cultural context, small enterprises received a role of absolute marginality, assuming that in a modern industrial economy, they could only play an interstitial or subordinate role concerning large enterprises⁵.

Even medium enterprises were not considered as a particular category of enterprise in their own right but only as growing businesses⁶. Furthermore, outside the protective umbrella of a large enterprise, the failure rate of small businesses is high⁷.

Along with the dominant line of thinking relative to the presumed economic superiority of big businesses⁸, few leading economic scientists believe small businesses have a vital role in the productive context.

2. See P. Bianchi, *La rincorsa frenata. L'industria italiana dall'unità alla crisi globale*, Bologna, 2013, p. 75.

3. See *ibidem*.

4. See G. Becattini, *Introduzione*, a J. Steindl, *Piccola e grande impresa. Problemi economici della dimensione d'impresa*, Milano, 1991, p. 1.

5. See M. Bellandi, *Mercati, industrie e luoghi di piccola e grande impresa*, Bologna, 2003, p. 122.

6. See *ivi*, p. 123.

7. See *ibidem*.

8. The contrast between big business and small business has been the subject of important studies by scholars of economic science since the 19th century: for an analysis of the economic doctrine on this point, see G. Becattini, *Introduzione*, a J. Steindl, *Piccola e grande impresa. Problemi economici della dimensione d'impresa*, p. 16.

Alfred Marshall was the first to note the critical issues related to an unsatisfactory analysis of the advantages of a division of labor and production on a larger scale.

He maintained the necessity to overcome the presumed superiority of a big business over small⁹.

From the European context, the original founding Treaty of the European Community was signed in Rome on March 25, 1957. According to Article 2 of the Treaty, it is the community that should promote, through the instauration of a common market and gradual alignment of the economic policies of the member states, a harmonious development of economic activities throughout the community.

These tasks lead to a continuous and balanced expansion, stability of growth, ever-increasing improvement of living standards, and closer relations between all the states involved.

No explicit reference is made to the industrial policy¹⁰, which can partly be explained by the fact that the Treaty of Rome was, at the time, permeated by the idea of creating a large, liberalized area^{11,12}. The term “industrial policy”, the exact definition of which is still a matter of debate among economists¹³, has only recently been added to the European Union’s (EU) lexicon.

In the 1970s, two European Commissioners, Guido Colonna di Paliano and Altiero Spinelli, were the first to introduce specific initiatives related to the industrial sector and the so-called Colonna Report (or Colonna Memorandum), Communication of the European Commission of March 18, 1970, n. 100, Principles and Guidelines for the Community’s Industrial Policy.

9. See A. Marshall, *Principles of Economics*, 8th ed., London, 1920. Other economic scholars have highlighted the importance of small businesses, for example, L. Harmon Ziegler, *The Politics of Small Business*, Washington D.C., 1961; E.M. Schumacher, *Small is beautiful*, London, 1972; P.M. Townroe, N.J. Roberts, *Local-external economies for British manufacturing Industry*, Westmead, 1980; W.G. Sengenber, W. Lovman, M.J. Piore, *The Re-emergence of Small Enterprises. Industrial Restructing*, in *Industrialised Economies*, Geneva, 1990, p. 1 ss.; G. Becattini, *La fioritura della piccola impresa ed il ritorno dei distretti*, in *Economia e politica industriale*, 1999, p. 5 ss.; G. Sapelli, *Elogio della piccola impresa*, Bologna, 2013.

10. See G. Colonna, *La politica comunitaria delle infrastrutture industriali*, Roma, 1969, p. 7.

11. See *ibidem*.

12. See *ibidem*, who states that at the end of the 1950s, the economic model the Authors of the Treaty referred to was a model of average industrialization and not of advanced industrialization.

13. See G. De Blasio, *Politica industriale e indotto*, in *Analisi giuridica dell’economia*, 2011, p. 229, who observes that Lotti (2008) compiles an illustrative list of definitions, from which a considerable heterogeneity is evident, while according to Adams and Klein (1983), industrial policy includes everything useful to stimulate growth and competitiveness; for Geroski (1989), it instead encompasses a wide range of supply-side initiatives, often varying with each other, designed to improve market performance but in different, inconsistent ways.

The Colonna Report provides a detailed analysis of the state of the European industrial sector and some preliminary indications for formulating an EU-wide industrial policy; however, the subject of “industrial policy” was carefully avoided.

The Report was derived from several guiding principles¹⁴ and objectives comprising introduction of measures to support and stimulate industrial activities.

The objective was to consolidate the foundations of Europe’s political and economic unity, maintain adequate levels of economic growth, and free European industries from technological dependence on the United States (US)¹⁵.

The Colonna Report observes that in the US, medium-sized companies significantly contribute to technological innovation and dynamism in the economy.

It addresses the critical question of the “size gap” of European companies compared to US companies, emphasizing the need to create companies that could operate on a European scale and favoring mergers between companies with capital from different member states¹⁶.

In 1972, Altiero Spinelli held a conference in Venice on the complex issue of the industrial sector, entitled Industry and Society in the European Community.

The conference made such an impact that the European Council requested the Commission draw up specific proposals on the subject according to Article 308 Treaty EC (Article 235), allowing the community to act without a specific legislative framework¹⁷.

These proposals were put forward, debated, and approved in a “program of action in the political, industrial and technological field” of 1973.

The program also prioritized the liberalization of the regime of public tenders, abolition of fiscal barriers, cooperation between businesses of member states, and supporting measures in the research and development sectors.

In 1978, the European Commission issued Communication n. 255 on June 22, 1978 (the so-called Davignon Report, named after European Commissioner Etienne Davignon).

The Communication emphasized that the competitiveness of European industrial enterprises was closely linked to the industry’s capacity and capability

14. See L. Perrotti, *L’industria*, in S. Cassese (a cura di), *Trattato di diritto amministrativo*, Milano, 2003, p. 3516.

15. See *ibidem*.

16. See F. Gobbo, C. Pozzi, *Liberalizzazione e politica industriale*, in *Economia e politica industriale*, 2005, p. 59.

17. See L. Perrotti, *L’industria*, in S. Cassese (a cura di), *Trattato di diritto amministrativo* p. 3517.

to demonstrate using new technologies, especially small- and medium-sized enterprises (SMEs)¹⁸.

The report emphasized that the competitiveness of European industrial enterprises should be considered “typical businesses and not the exception to the rule”¹⁹.

The same SMEs “therefore have a major role to play in the growth strategy of any sector in which their small size is not an obstacle to the introduction of the most advanced production methods”²⁰.

With the enactment of the Single European Act of 1986, specific measures to consolidate the single market and legal regulation for SMEs were implemented, stipulating, “such directives shall avoid imposing administrative, financial, and legal constraints in a way which would hold back the creation and development of small- and medium-sized enterprises”²¹.

The Maastricht Treaty of 1992, in Article 157, addresses the question by setting specific aims for the EU’s industrial policies, defined as policies to support the competitiveness of industrial enterprises.

The aim was to accelerate the adaptation to structural changes in the market and demand while promoting an environment favorable to enterprises’ initiative and development, especially small and medium-sized ones.

Furthermore, the Treaty aimed to encourage better utilization of the industrial potential of innovation, research, and technological development policies.

Thus, the Maastricht Treaty of 1992, which incorporated the indications of the Bangemann Report (European Commission Communication of November 16, 1990, n. 556 on Industrial Policy in Open and Competitive Environment. Orientations for a Community Solution), introduced a new title (Title XIII) explicitly dedicated to industrial policy, which Article 130 refers to as small enterprises.

Therefore, it was necessary to provide a “dynamic policy” indicating specific measures to enable small enterprises to compete in the internal and international markets.

The notion of industrial policy is closely linked to that of competitiveness²².

In other words, industrial policy is once again entrusted to individual states

18. Communication of the European Commission 22 June 1978, n. 255, p. 2.

19. Ivi, p. 2.

20. Ivi, p.11.

21. Article 21, 2.

22. See L. Perrotti, *L'industria*, in S. Cassese (a cura di), *Trattato di diritto amministrativo*, p. 3519. See also F. Gobbo, C. Pozzi, *Liberalizzazione e politica industriale*, in *Economia e politica industriale*, p. 57. In a comparative perspective see A.M. Bernini, *Intervento statale e privatizzazioni. Un panorama comparativo*, Padova, 1996.

while giving the community the task of promoting and coordinating it to make European industries more competitive²³.

The Treaty on the Functioning of the European Union of 2007²⁴, Article 6, places industry in areas where the EU has the competence to act to support, coordinate, or supplement the actions of the member states.

The subsequent Article 153, 2, lett. b, states that the European Parliament and the European Council may, in specific sectors of importance for the market and society, adopt minimum requirements applicable progressively, considering the conditions and technical rules existing in each member state.

States should also avoid imposing administrative, financial, and legal constraints to hold back the formation and development of SMEs.

Article 173 stipulates that the EU and its member states will ensure that the necessary conditions for the competitiveness of the EU's industry are in place.

To this end, within a system of open and competitive markets, their action aims to rush the industry's adaptation to structural changes and to promote an environment favorable to the initiative and the development of enterprises throughout the EU, including SMEs. Additional actions include promoting a favorable environment for cooperation between enterprises and fostering better utilization of the industrial potential of innovation, research, and technological development policies²⁵.

Moreover, from a procedural perspective, regarding the role of the member states, the Treaty provides that the states consult each other in liaison with the Commission and coordinate their actions as needed. At the same time, the Commission may take any beneficial initiative to promote such coordination²⁶.

Furthermore, the European Parliament and the Council may decide on specific measures, to the exclusion of any harmonization of the laws and regulations of the member states (Article 173, 2).

A further provision related to small enterprises is found in Article 179,2, which indicates that the EU shall encourage undertakings, including SMEs, research centers, and universities, in their efforts for quality research and technological development.

At the European level, the regulatory framework for smaller business

23. See R. Gallo, F. Silva, *Sul coordinamento della politica industriale*, in *Economia e politica industriale*, 2005, p. 11.

24. The Treaty of Lisbon (Treaty on European Union and Treaty on the Functioning of the European Union) was signed in Lisbon on December 13, 2007.

25. For an analysis on this point, see E. Picozza, S. Oggianu, *Politiche dell'Unione europea e diritto dell'economia*, Torino, 2013, p. 91.

26. See *ibidem*.

enterprises appears to be rather uneven, episodic, and fragmented from the outset.

2. Legal regulation of SMEs in Europe; small and medium-sized businesses and the Small Business Acts: The principle of “Think Small First”, which is the key step toward the legal recognition of the importance of small businesses for the European economy

Between 2005 and 2007, Europe gave rise to a deeper cultural definition regarding smaller businesses; this occurred before the legal designation.

The first definition and legal recognition of their problems can be found in the European Charter for Small Enterprises, signed in Feira (Portugal) in 2000²⁷, and also in European Commission Recommendation of 6 May 2003, concerning the definition of micro, small and medium-sized enterprises.

This Recommendation confirms in Article 1 of the Annex that “An enterprise is considered to be any entity engaged in an economic activity, irrespective of its legal form. This includes, in particular, self-employed persons and family businesses engaged in craft or other activities, and partnerships or associations regularly engaged in an economic activity”, whilst in Article 2 of the same Annex establishes the “Staff headcount and financial ceilings determining enterprise categories”, which fits “1. The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. 2. Within the

27. On this point, see A. Pezzini, M. Di Cesare, *Le piccole e medie imprese in Europa. Innovazione, ricerca e sviluppo tecnologico, responsabilità sociale e finanza d'impresa*, Soveria Mannelli, 2003, pp. 45-46, which present the key principles of the Charter in six points. These papers also recognize the dynamism of small businesses in responding to new market demands and creating employment. This is an affirmation of the importance of small businesses in promoting social and regional development and is, simultaneously, an example of initiative and commitment. Recognition that the spirit of enterprise is, at all levels of responsibility, a valid and productive human ability. A just reward and tribute for successful businesses. Recognition that taking initiatives and risks can lead to failure should be considered as an opportunity to learn – recognition of the value of knowledge, work, and flexibility for the new economy. The authors then specify that the Charter lists 10 courses of action to improve businesses based on their relative needs (p. 46). These are briefly identified as education and business training; faster and less expensive start-ups; better legislation and regulation; provision of expertise and greater benefits from the internal market; fiscal and financial issues; increased technological capacity of businesses; successful e-business models and support for the most innovative small businesses; and a stronger and more effective representation of the interests of small businesses at the EU and national levels.

SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million. 3. Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million”.

However, it was only in 2008 that Europe made the first significant step concerning legal regulation for small businesses by issuing the first Small Business Act for Europe (SBA)²⁸, revised in 2011.

The SBA²⁹ marked a genuine and vital point of departure in the consideration that Europe should take on evaluating the full potential of European SMEs.

These have a lower level of productivity than their American equivalents; in fact, companies survived increased employment by an average of 60% by the seventh year, whereas the corresponding data in Europe were approximately between 10% and 20%³⁰.

To construct a legal and economic environment favorable to smaller enterprises, the SBA emphasized that a prerequisite for any consideration is that in such a context, “the conviction that achieving the best possible framework conditions for SMEs depends first and foremost on society’s recognition of entrepreneurs. The general climate in society should lead individuals to consider the option of starting their own business as attractive and acknowledge that SMEs contribute substantially to employment growth and economic prosperity”³¹.

For this reason, “[B]eing SME-friendly should become a mainstream policy, based on the conviction that the rules must respect the majority of those who will use the ‘Think Small First’ principle”³².

The expression “Think First Small” indicates the key principle for a new legal regulation to strengthen the economic activities of small businesses.

It represents an initial acknowledgment and realization, on the part of the European regulator, of the necessity to restore dignity to an economic and social sector of primary importance.

Around this principle, the SBA developed into a true Decalogue of further

28. Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee, and the Committee of the Regions, “Think Small first”, a “Small Business Act” for Europe, 25 June 2008, n. 394.

29. On this point, see C.E. Pupo, *The Small Business Act and the work in progress of its activation*, in *Analisi giuridica dell’economia*, 2014, p. 135; G. Capuano, *The Small Business Act and the use of online contracts to combat the crisis*, in *Economia e Diritto del terziario*, 2014, p. 29.

30. Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, “Think Small First”, a “Small Business Act” for Europe, 27 June 2008, n. 394, p. 7.

31. *Ibidem*.

32. *Ibidem*.

principles³³, becoming the foundation of a slow but continuous construction, which, from 2008, began developing into a specific regulatory framework homogeneous for this type of enterprise.

In particular, in Principle III, relating to “Design rules according to the ‘Think Small First’ principle”, the Commission indicates that the EU and the individual member states must formulate rules “by taking into account SMEs’ characteristics when designing legislation, and simplify the existing regulatory environment. The most burdensome constraint reported by SMEs is compliance with administrative regulations. Indeed, SMEs bear a disproportionate regulatory and administrative burden compared to larger businesses. It has been estimated that where a big company spends one euro per employee because of regulatory duty, small businesses might have to spend, on average, up to 10 euros. 36% of EU SMEs report that red tape has constrained their business activities over the past two years”³⁴.

On this point, the Commission reserves the right to monitor compliance with the protocol on applying the principles of subsidiarity and proportionality³⁵.

They also aim to “ensure that policy results are delivered while minimizing costs and burdens for business, including by using a smart mix of tools such as mutual recognition and self- or co-regulation” and to “rigorously assess the impact of forthcoming legislative and administrative initiatives on SMEs (SME test) and take relevant results into account when designing proposals”, as well as “make use of flexibility provisions aimed at SMEs when implementing EU legislation and avoid ‘gold-plating’”³⁶.

33. The Decalogue contains the following Principles: “I. Create an environment in which entrepreneurs and family businesses can thrive and entrepreneurship is rewarded; II. Ensure that honest entrepreneurs who have faced bankruptcy quickly get a second chance; III. Design rules according to the ‘Think Small First’ principle; IV. Make public administration responsive to SMEs’ needs; V. Adapt public policy tools to SME needs: facilitate SMEs’ participation in public procurement and better use State Aid possibilities for SMEs; VI. Facilitate SMEs’ access to finance and develop a legal and business environment supportive of timely payments in commercial transactions; VII. Help SMEs benefit more from the opportunities offered by the Single Market; VIII. Promote the upgrading of skills in SMEs and all forms of innovation; IX. Enable SMEs to turn environmental challenges into opportunities; X. Encourage and support SMEs to benefit from the growth of markets”.

34. Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, “Think Small First”, a “Small Business Act” for Europe, 27 June 2008, n. 394, p. 7.

35. Protocol n. 2 of the Treaty on the functioning of the EU on the application of the principles of subsidiarity and proportionality.

36. Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, “Think Small First”, a “Small Business Act” for Europe, 27 June 2008, n. 394, p. 7.

Furthermore, of particular interest is Principle IV, which affirms, “The EU and member states should make public administrations responsive to SME needs, making life as simple as possible for SMEs, notably by promoting e-government and one-stop-shop solutions. Modern and responsive public administrations can make a major contribution to the success and growth of SMEs by saving them time and money and hence freeing resources for innovation and job creation”. In particular, “E-government and one-stop shops [...] have the potential to help improve service and reduce costs. The ongoing implementation process of the Services Directive will contribute to making life easier for SMEs and requires Member States to set up points of single contact, to reduce in number and lighten authorization schemes, and to eliminate regulatory barriers to the development of service activities”³⁷.

Concerning new digital tools that SMEs can use to increase their business, the Commission invites member states to “Ensure full and timely implementation of the Services Directive, including the setting up of points of single contact, through which businesses can obtain all relevant information and complete all necessary procedures and formalities by electronic means”³⁸.

Moreover, concerning the successive Principle VIII, “The EU and Member States should promote upgrading skills in SMEs and all forms of innovation. They should encourage investment in research by SMEs and their participation in R&D support programs, transnational research, clustering and active intellectual property management by SMEs” the Commission invites member states to face the fact that “the societal need to always provide young people with essential skills, such as reading, writing, natural sciences, management, technical, ICT, and language skills and enable them to be creative. SMEs suffer from the lack of skilled labor in the field of new technologies. In this context, the European Reference Framework on key competencies for lifelong learning, which aims at

37. Ivi, p. 9.

38. *Ibidem*, invites member states to “reduce the level of fees requested by the Member States’ administrations for registering a business, taking inspiration from EU best performers; continue to work to reduce the time required to set up a business to less than one week, where this has not yet been achieved; accelerate the start of SMEs’ commercial operations by reducing and simplifying business licenses and permits. More specifically, Member States could set a maximum deadline of 1 month for granting these licenses and permits, except in cases justified by serious risks to people or the environment; refrain from asking SMEs for information, which is already available within the administration unless it needs to be updated; make sure that a micro-business is not asked to participate in a statistical survey under the responsibility of the State, regional, or local statistical office more than once every three years, provided that the needs for statistical and other types of information do not require otherwise; establish a contact point to which stakeholders can communicate rules or procedures that are considered to be disproportionate and/or unnecessarily hinder SME activities”.

offering the necessary basic skills to all young people, needs to be implemented. The European Cohesion Policy supports actions to promote the adaptability of workers, entrepreneurs, and enterprises with some €13.5 billion over the period 2007-2013. A significant part of this amount is directly targeted at SMEs”.

In this context, “the Commission is working on an overview of future skills needs in the EU. Linked to the skills shortage is the unexploited potential for research and innovation [...]. It is also necessary to encourage active intellectual property management by SMEs, for instance, by enabling e-invoicing and e-government transactions. To translate this principle into practice: the Commission [...] will encourage active participation of SMEs in the framework of the activities carried out by the European Institute of Innovation and Technology (EIT) to enable them to benefit from the knowledge transfers fostered by the EIT”³⁹.

Member states are also invited to encourage “the efforts of SMEs to internationalize and become high growth enterprises including through participation in innovative clusters” and “promote the development of SMEs’ competencies in the research and innovation field by means of, e.g. simplified access to public research infrastructure, use of R&D services, recruitment of skilled employees and training, as allowed for in the new Community Framework for State Aid for research, development, and innovation” as well as “support the development of an electronic identity for businesses, to enable e-invoicing and e-government transactions”⁴⁰.

The need to build a European industrial policy is then reaffirmed in the Review of the SBA (the Communication from the Commission to the European Parliament, the Council, Economic and Social Committee of the Regions, Review of the “Small Business Act” for Europe, 23 February 2011, n. 78).

The Review aims to improve the business environment, especially for SMEs, and foster the development of an industrial base capable of competing worldwide.

In the SBA Review, the European Commission also strongly emphasizes the need for SMEs to use e-government systems within a legal framework that must increasingly become a Smart Regulation (i.e., an “intelligent administration”⁴¹),

39. Ivi, p. 15.

40. Ivi, p. 16.

41. As noted, the reference to the Smart Regulation is contained in the Communication from the European Commission to the European Parliament, the Council, the European and Social Committee, and the Committee of the Regions, Smart Regulation in the European Union, Brussels, 8 October 2010, n. 543. This arises by considering that “The economic and financial problems of the last two years have contained important lessons for regulatory policy. Most importantly, they have confirmed that markets do not exist in isolation. They exist to serve a purpose, which is to deliver sustainable prosperity for all, and they will not always do this on their own. Regulation has a positive and necessary role to play. The crisis has highlighted the need to address incomplete, ineffective, and underperforming regulatory measures and, in many cases, to do so urgently. Our

more specifically, “Smart regulation needs to become a reality for European SMEs. Implementing the ‘Think Small First’ principle remains the core principle of the SBA. It implies simplifying the regulatory and administrative environment in which SMEs operate, notably by designing rules according to it, including the ‘only once’ principle or by using tools like e-government and one-stop-shop solutions”⁴².

Within a process of building a new regulatory system of a legal-regulatory nature, the European Commission, therefore, emphasizes that every public administration must intensify its efforts in listening to and understanding the real needs of the smaller enterprise by increasing the use of digital solutions such as e-Government.

More specifically, it recalls how the e-Government Action Plan at a European level includes “Efforts to make public administrations responsive to SMEs need to be strengthened, in particular by increasing the use of e-government solutions. The e-Government Action Plan sets out a wide range of actions that will allow SMEs to spend less time on administrative procedures, including promoting cross-border e-procurement. Similarly, the Commission will work with member states to further develop the ‘Points of Single Contact’, aimed at considerably facilitating such procedures, into user-friendly e-Government portals that allow for electronic completion, including cross-border, of all necessary administrative requirements. The Commission will ensure that SME

approach to regulation must promote the interests of citizens and deliver on the full range of public policy objectives, from ensuring financial stability to tackling climate change. EU regulations also contribute to business competitiveness by underpinning the single market, eliminating the costly fragmentation of the internal market because of different national rules” (p. 1). Regarding “First, Smart Regulation whole policy cycle, from the design of a piece of legislation to implementation, enforcement, evaluation, and revision. We must build on the strengths of the impact assessment system for new legislation; however, we must match this investment with similar efforts to manage and implement the body of existing legislation to ensure that it delivers the intended benefits. This requires a greater awareness by all actors of the fact that implementing existing legislation properly and amending it in the light of experience is as important as the new legislation we put on the table. Second, smart regulation must remain a shared responsibility of the European institutions and of Member States; ... Third, the views of those most affected by regulation have a key role to play in smart regulation. The Commission has made great strides in opening its policy making to stakeholders” (p. 1). Regarding SMEs, the European Commission indicates how “At the same time, given that we depend on businesses, in particular small and medium enterprises, to get us back on the path to sustainable growth, we must limit [the] burdens for them to what is strictly necessary and allow them to work and compete effectively. In short, getting [the] legislation right is essential if we are to deliver the ambitious objectives for smart, sustainable, and inclusive growth set out by the Europe 2020 Strategy” (p. 1).

42. Communication from the Commission to the European Parliament, the Council, economic and Social Committee of the Regions, Review of the “Small Business Act” for Europe, 23 February 2011, n. 78, p. 6.

expertise is fully available when assessing the impact of new proposals on SMEs while taking into account differences in the size of enterprises, where relevant; promote across the EU the application of the ‘only once’ principle whereby public authorities and administrative bodies should refrain from requesting the same information, data, documents, or certificates, which have already been made available to them in the context of other procedures⁷⁴³.

However, the digital dimension of the legal regulation of SMEs is picked up by the European Commission when it states that they should support them “to benefit from the Single Market, including the Digital Single Market and the growth of markets outside the EU while facing the challenge of a sustainable economy. Moreover, the Europe 2020 strategy sets out several actions to improve the EU’s competitiveness vis-à-vis its main trading partners, notably through establishing an industrial policy for the globalization era and a renewed trade strategy, and to promote a resource-efficient Europe. Finally, the Communication ‘Towards a Single Market Act’ sets ambitious objectives to improve the Single Market and presents a comprehensive package of measures⁷⁴⁴.

Furthermore, from the perspective of consolidating digital innovation, “[t]he Commission is taking action to ensure that optimal conditions exist for SMEs to engage in cross-border trade, including via the Internet. The Single Euro Payments Area (SEPA) will allow SMEs to benefit from simpler payment arrangements with reduced costs and no need to use more than one bank account within the single market. SEPA also provides a platform for developing pan-European e-invoicing and its mass adoption by SMEs; the Commission also underlines the need to sustain its Digital Agenda, the potential of online business, with a specific target of 33% of SMEs conducting online purchases/sales by 2015. Moreover, to promote cheap, simple, and quick redress and thus offer an efficient alternative to more costly and lengthy court proceedings, the Commission is currently preparing a legislative proposal to promote Alternative Dispute Resolution (ADR) schemes in the EU, including the possible development of an EU-wide online dispute resolution system for e-commerce transactions covering both B2B and B2C situations⁷⁴⁵.

Furthermore, regarding the profile that characterizes the definition of Smart Regulation for SMEs and to make it a reality for European SMEs, strengthening the SME Test is required.

This test aims to ascertain “its impact assessment procedure to ensure that impacts on SMEs are thoroughly analyzed and taken into account in all relevant

43. Ivi, p. 7.

44. Ivi, p. 11.

45. Ivi, p. 12.

legislative and policy proposals, with a clear indication of quantified effects on SMEs, whenever possible and proportionate⁴⁶.

In fact, “the differences between micro, small, and medium-sized enterprises need to be recognized and be taken into account when applying the ‘SME Test’, and, where appropriate, specific measures such as reduced fees or simplified reporting obligations should be envisaged. Whenever the option to implement these measures is left to the Member States, they should use them⁴⁷.”

Other proposed organizational solutions include The One-stop-shop, “where SMEs can apply for European, national, and local grants⁴⁸”, resorting to solutions of the Credit Ombudsman-type “to further facilitate the dialogue between SMEs and credit Institutions⁴⁹”, and holding a European SME Week aimed at “providing a pan-European Platform with more than 1,500 events and 3 million participants⁵⁰”.

Additional solutions include the Erasmus for Young Entrepreneurs’ Program, launched in 2009, that “offers on-the-job training to nascent and new entrepreneurs with a view to fostering cross-border networking and business cooperation with experienced entrepreneurs⁵¹”, as well as the European Network of Female Entrepreneurship Ambassadors formed by the European Commission in 2009 “to inspire more women to become entrepreneurs⁵²”.

Similarly, the establishment of a specific SBA Advisory Group, composed of “representatives of Governments and business organizations to contribute to evaluating and reporting on the uptake of the SBA, to step up efforts for the

46. Ivi, p. 6.

47. Ivi, p. 7, which also states that at the general regulatory level, “Similarly, Member States should avoid ‘gold plating’, i.e., exceeding the requirements of EU legislation when transposing Directives into national law. The Commission confirms its readiness to assist the Member States in this task. To ensure that the regulatory framework is fit for purpose and to identify the cumulative effects of legislation, the Commission will apply ‘fitness checks’ to existing legislation whereby evaluations of individual pieces of legislation are complemented with a more comprehensive approach. This will help identify inconsistencies and obsolete or ineffective measures and will further reduce the burden on SMEs, including those working in nonindustrial sectors, for instance, in the field of trade or crafts. Such an approach is currently being developed in the area of services to test the overall functioning of the single market for services, notably from the viewpoint of SMEs. Simplification is a major objective. By October 2011, the Commission will simplify the transparency and reporting requirements for smaller listed companies. Moreover, the Commission is assessing the simplification of the audit requirements for small firms to follow up the Green Paper on Audit policy”.

48. Ivi, p. 11.

49. *Ibidem*.

50. Ivi, p. 4.

51. *Ibidem*.

52. *Ibidem*.

dissemination of the information on SME-policy actions and promotion of the exchange of good practices. In this context, it will further develop the SME Performance Review, focused notably on the measures in the SBA Action Plan, in order to monitor and assess Member States' performance in implementing the SBA on the basis of a wide range of success indicators"⁵³.

The proposal to institute an "annual SME Assembly" is closely linked to the SBA good practices conference "in order to mobilize all relevant stakeholders in the implementation of the SBA and to foster dialogue between them"⁵⁴, as well as establishing a "body in charge of coordinating SME issues across different administrations ('SME Envoy'), provided with adequate human resources and having a high standing within the administration itself"⁵⁵.

Furthermore, the institution of the SME Finance Forum aims at "bringing together SME representatives, banks, market operators and other financial institutions, including the EIB, in order to address the various practical obstacles faced by SMEs when attempting to get credit"⁵⁶.

The questions raised and the solutions proposed by the Review of the SBA also find their place and reference in the same time frame in the enactment of a Digital Agenda for Europe, introduced by the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, of May 19, 2010, n. 245, designed "to chart a course to maximize the social and economic potential of ICT, most notably the [I]nternet, a vital medium of economic and societal activity: for doing business, working, playing, communicating and expressing ourselves freely. Successful delivery of this Agenda will spur innovation, economic growth, and improvements in daily life for both citizens and businesses. Wider deployment and more effective use of digital technologies will thus enable Europe to address its key challenges and will provide Europeans with a better quality of life through, for example, better health care, safer and more efficient transport solutions, [a] cleaner environment, new media opportunities, and easier access to public services and cultural content"⁵⁷.

53. Ivi, p. 18.

54. *Ibidem*.

55. *Ibidem*.

56. Ivi, p. 8. On the subject of obstacles, see Legal Obstacles in Member States to Single Market Rules, European Parliament, Luxembourg, November 2020.

57. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, Digital Agenda for Europe, 19 May 2010, n. 245, pp. 1-2, where it is specified that the Digital Agenda for Europe arises from the crisis that "has wiped out years of economic and social progress and exposed structural weaknesses in Europe's economy. Europe's primary goal today must be to get Europe back on track. To achieve a sustainable future, it must already look beyond the short

Moreover, “this great potential of ICT can be mobilized through a well-functioning virtuous cycle of activity. Attractive content and services need to be made available in an interoperable and borderless [I]nternet environment. This stimulates the demand for higher speeds and capacity, which in turn creates the business case for investments in faster networks. The deployment and take-up of faster networks open the way for innovative services exploiting higher speeds”⁵⁸.

European regulators have observed that the impact of digitalization on the market can give rise to important and profound transformations: “The Internet is borderless, but online markets, both globally and in the EU, are still separated by multiple barriers affecting not only access to pan-European telecom services but also to what should be global Internet services and content. This is untenable. First, the creation of attractive online content and services and its free circulation inside the EU and across its borders are fundamental to stimulate the virtuous cycle of demand. However, persistent fragmentation is stifling Europe’s competitiveness in the digital economy. It is[,] therefore[,] not surprising that the EU is falling behind in markets such as media services, both in terms of what consumers can access and in terms of business models that can create jobs in Europe. Most of the recent successful Internet businesses (such as Google, eBay, Amazon, and Facebook) originate outside of Europe. Second, despite the body of key single market legislation on e-commerce, e-invoicing, and e-signatures, transactions in the digital environment are still too complex, with inconsistent implementation of the rules across Member States. Third, consumers and businesses are still faced with considerable uncertainty about their rights and legal protection when doing business online. Fourth, Europe

term. Faced with demographic ageing and global competition, we have three options: work harder, work longer, or work smarter. We will probably have to do all three, but the third option is the only way to guarantee increasing standards of life for Europeans. To achieve this, the Digital Agenda makes proposals for actions that need to be taken urgently to get Europe on track for smart, sustainable, and inclusive growth. Its proposals will set the scene for the longer-term transformations that the increasingly digital economy and society will bring about”. For an update doctrine on the topic on transport see S. Zunarelli, *I servizi di trasporto marittimo*, and *I servizi di trasporto aereo* in S. Zunarelli, A. Romagnoli, A. Claroni (a cura di), *Casi e materiali di diritto pubblico dei trasporti*, Bologna, 2018, p. 157 ss., p. 189 ss.; C. Alvisi, A. Claroni, *Analisi giuridica di alcune fattispecie della cd. economica collaborativa nel settore dei trasporti e del turismo*, in *New Policies and Practices for European Sharing Cities*, Bologna, 2019, p. 239 ss.; M. Musi, *An Overview of Transport Law Regulatory Policies. The Search for the New Answers to Old Problems and Possible Solution to the Challenge Posed by Technological Evolution, The Pandemic and Brexit*, in *Diritto marittimo*, 2021, p. 268 ss.

58. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, Digital Agenda for Europe, 19 May 2010, n. 245, p. 4.

is far from having a single market for telecom services. The single market, therefore, needs a fundamental update to bring it into the Internet era”⁵⁹.

The European Economic and Social Committee on Promoting SMEs in Europe with a special focus on a horizontal legislative SME approach and respect of the SBA’s “Think Small First” of January 17 and 18, 2018⁶⁰, provides evidence of the difficulty of implementing an effective strategy for smaller companies.

Although in 2011, the European Commission issued the Review of the SBA and, in 2014, launched a public consultation on ways of applying it, “that progress in the real application of the Think Small First principle remains fragmented and far from being complete. This implementation delay is very dangerous because SMEs are currently facing more challenges than ever harsh competition, shortage of skilled labor, new forms of work and of consumption, an increasingly complex and intense flow of information, limited resources for innovation, constant downgrading of the entrepreneur’s role, volatile financial markets, complicated access to finance and high dependence on the external environment, [and] limited bargaining power”⁶¹.

Moreover, “The SME situation is further aggravated by an overly complex process of technical standardization, intellectual property, general data protection rules, market abuses by global actors, and impeded participation in EU/national public contracts and global value chains. More efficient solutions should be designed, especially where the SMEs are negatively affected by structural problems and market failures”: furthermore, regarding digitalization and the technological developments, “it entails, including e-commerce, present not only valuable opportunities for SMEs but also pose important challenges, prompting them to change their culture, activities, and business models. It would be highly desirable for the economic sectors and regions that are most critical for SMEs to be involved more closely in Industry 4.0”⁶².

Additionally, from the point of view of achieving Smart Regulation for SMEs, the opinion states, “When excessive, the European, national, regional,

59. Ivi, p. 7.

60. The opinion of the European Economic and Social Committee on Promoting SMEs in Europe with a special focus on a horizontal legislative SME approach and respect of the SBA’s “Think Small First”, 17 and 18 January 2018, p. 3.

61. Ivi, p. 4. See C. Golino, *Il mercato finanziario per le piccole e medie imprese tra difficoltà della crisi economica e nuove prospettive*, in *Forum di Quaderni Costituzionali Rassegna*, 2014, p. 1 ss., and A.L. Niutta, *Specificità delle parole e mercato finanziario. Spunti sulla nuova normativa europea sulla trasparenza del mercato e la tutela del cliente*, in U. Morera, M. Sciuto (a cura di), *Le parole del diritto commerciale. Law and Legal Institution*, Torino, 2018.

62. The opinion of the European Economic and Social Committee on Promoting SMEs in Europe with a special focus on a horizontal legislative SME approach and respect of the SBA’s “Think Small First”, 17 and 18 January 2018, p. 3.

and local regulatory burdens remain a major obstacle for SMEs as they tend to be poorly equipped to deal with these sorts of problems. The EESC supports cutting the red tape and constraints on small, medium-sized and micro-enterprises and the public. The Commission should focus on quality rather than quantity and prioritize reductions in red tape, which has been seen to translate into a cost on businesses, a brake on their competitiveness, and an obstacle to innovation and job creation. It goes without saying that when such steps are taken, consideration must be given to the aim and purpose for which obligations were put in place. The EESC insists that compliance procedures should not be unnecessarily costly or lengthy. The silent consent principle must be promoted when legislating at the European, national, and regional levels. MS needs to be encouraged to keep administrative taxes to a level not exceeding the administrative costs⁶³.

In this sense, “The intention stated by the EC in the SBA review to ‘explore the possibility for reducing gold-plating by MS’ must be implemented in practice, in accordance with the communication on Smart Regulation, without curtailing the regulations on protecting the public, consumers and workers, or gender and environmental standards, including by encouraging the MS to give a particular central body responsibility for monitoring [...]. The EESC calls on European and national policymakers to ensure systematic scrutiny of new regulations and their implementation by representatives of EU, national, regional and local business associations. The reduction of unnecessary costs and burdens should be based on evidence from a ‘case-by-case’ assessment. Appreciating the crucial importance of business transfers for SMEs and especially family businesses, the EESC calls for swift measures to facilitate and streamline them at reasonable costs. The culture of risk-taking must be wider promoted, including by creating a more favorable legislative second-chance framework⁶⁴.”

The new paths for growing and strengthening SMEs are, according to the Committee, through digitalization and technological developments: “Digitalization and the technological developments it entails, including e-commerce, present not only valuable opportunities for SMEs but also pose important challenges, prompting them to change their culture, activities and business models⁶⁵.”

From a financial perspective for small businesses, “The innovative platforms for peer-to-peer lending have great potential as an alternative source of funding for SMEs, making non-bank forms of financial mediation possible. However, the high potential of these new forms of lending is still hampered by unclear areas of

63. Ivi, p. 6.

64. Ivi, p. 7.

65. Ivi, p. 3.

law and regulation. The EESC calls for an international effort by policymakers, regulators, and interested parties to clarify the rules that govern key financial intermediaries in this area, without generating a major regulatory burden⁶⁶.

3. A new Industrial Strategy for Europe: The Digital Single Market (and the Review); challenges and digital opportunities for small businesses

Technological innovation has resulted in a sudden and unprecedented increase in economic and commercial exchanges, forcing European regulators to rethink the traditional market concept as a new digital type of market appears in the European scene.

The digital market is a result of the ongoing technological revolution in social, mobile, analytics, and cloud (SMAC) technologies⁶⁷.

It is mainly based on the collection, elaboration, management, and diffusion of big data (or mega data, defined as large aggregations of data or digital information, often of a personal nature, which requires the use of powerful processors, software, and algorithms to be processed), aptly renamed the oilfields of the Third Millennium⁶⁸.

Technological innovation has significantly affected the traditional concept of the market.

It has been a cultural revolution, even prior to becoming an economic revolution for the society and entrepreneur.

Moreover, innovation is the characterizing trait of the entrepreneur, regardless of the size of the enterprise.

In the US, an entrepreneur is whoever forms a new business of a small dimension⁶⁹; in Common Law countries, the entrepreneurial spirit is usually

66. Ivi, p. 4.

67. See F. Saccomanni, *Crepe nel sistema. La frantumazione dell'economia globale*, Bologna, 2018.

68. See B. Rabai, *I "Big Data" nell'ecosistema digitale: tra libertà economiche e tutela dei diritti fondamentali*, in *Amministrare*, 2017, p. 407 ss.; A. Marciano, A. Nicita, G.B. Ramello, *Big Data and Big Techs: Understanding the Value on Information Platform Capitalism*, in *European Journal of Law and Economics*, 2020, p. 345 ss.; T. Schrepel, *Competition Law and Big Data. Imposing access to information in the Digital Market*, in *Common Market Law*, 2021, p. 21 ss.; C.E., Papadimitriou, *Digital Transformation e sistema industriale: alcune riflessioni sul settore bancario*, in *Rivista del Diritto del Risparmio*, 2021, p. 1 ss.; C.S. Hutchinson, *Potential abuse of dominance by Big Tech through their use of Big data and AI*, in *Journal of Antitrust Enforcement*, 2022, p. 443 ss.

69. P. Drucker, *Innovazione e imprenditorialità*, Sonzogno, 1986, p. 21. More recently see E.

identified with small businesses⁷⁰, and new, unexpected, and endless possibilities are what the digital technological revolution envisages.

Thus, the Digital Single Market represents a significant challenge for Europe to create new and different opportunities, including for SMEs; however, without proper legal regulation, it could be an insurmountable hurdle for them⁷¹.

As is still the case today, the non-accessibility to big data and the technological tools that enable its use by smaller companies could widen the gap between large multinationals and other industrial and commercial companies.

This has resulted in a crisis of European legal rules governing the right to free economic enterprises.

In this new context, the European Commission issued “A Digital Single Market Strategy for Europe” in 2015. The Strategy specifically stated, “A Digital Single Market is one in which the free movement of goods, persons, services, and capital is ensured and where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition and a high level of consumer and personal data protection, irrespective of their nationality or place of residence. Achieving a Digital Single Market will ensure that Europe maintains its position as a world leader in the digital economy, helping European companies to grow globally”⁷².

With the Digital Single Market, the Commission aims to make Europe the leader of the global digital economy⁷³.

Carbonara, E. Santarelli, T. Tran H., *Determinants of Novice, Portfolio, and Serial Entrepreneurship: An Occupational Choice Approach*, in *Small Business Economics*, 2020, p. 123.

70. P. Drucker, *Innovazione e imprenditorialità*, p. 27.

71. See E. Carbonara, M.R. Tagliaventi, *SMEs in the Digital Era: Opportunities and Challenges of the Digital Single Market*, Cheltenham, UK, 2023; G. Carli, J. Hartley, M.R. Tagliaventi, *Business Models and organizational choices for SMEs in the Digital Single Market*, in E. Carbonara, M.R. Tagliaventi (eds.), *SMEs in the Digital Era: Opportunities and Challenges of the Digital Single Market*, Cheltenham, UK, 2023.

72. Communication from the Commission to the European Parliament, the Council, the European economic and Social Committee, and the Committee of the Regions, A Digital Single Market Strategy for Europe, n. 192, 6 May 2015, p. 3.

73. Ivi, p. 3. The doctrine on the Digital Single Market is vast; see N. Vettas, *Competition and Regulation in Markets for Goods and Services: A Survey with Emphasis on Digital Markets*, in R. Blundell, E. Cantillon, B. Chizzolini, M. Vivaldi, W. Leininger, R. Marimon, L. Matyas, F. Steen (eds.), *Economics without Borders*, Cambridge, 2017, p. 194, which also specifies how “... it is important to try to clarify what the term ‘digital market’ really means and what (if anything) is really fundamentally new there and in online trade (or electronic-trade, e-trade). One way to approach and organize the various aspects of the issue is as follows. 1. A first category refers to cases where the Internet is used so that the end users has access to a good that is being offered (online digital form) [...] 2. A second category involves markets where the end good that will be consumed is not in digital form and instead the online operation merely facilitates searches and purchasing [...] 3. A third category may involve digital markets only at the wholesale level (B2B)

Article 3 of the TEU refers to the Digital Single Market as a part of the internal market⁷⁴; it becomes the emblem and banner of a specific Strategy that the Juncker Commission has put in place to open the traditional physical market to digital consumers and operators⁷⁵.

On this point, “In summer 2014, when running for Presidency of the European Commission, Jean-Claude Juncker announced ten priorities for his prospective Commission and a ‘Connected Digital Single Market’ ranked high amount them”⁷⁶.

The main idea was “extending the internal market to the growing digital world, which the notion of the Digital Single Market essentially entails, could seem attractive both economically and politically. Achieving this goal should stimulate trade and, therefore, economic growth”: in 2014, “the would-be President Juncker argues that by creating a connected Digital Single Market, we can generate up to 250 billion EUR of additional growth in Europe in the course of the mandate of the next Commission, thereby creating hundreds of thousands of new jobs, notably for younger job-seekers and vibrant knowledge-based society”⁷⁷.

The idea for the creation of a Digital Single Market is also based on the observation of specific digital backwardness, wherein only 4% of online services within the EU were cross-border⁷⁸; regarding SMEs in Europe, only 7% sold beyond their national borders, often due to extra costs they could not economically sustain⁷⁹.

[...] 4. Online auctions (at the retail or wholesale level) are also a distinct category. Auctions, even when organized offline, are market activities that operate on the basis of some clear and precise rules, and their conduct online mainly provides some gains in terms of lower costs” (pp. 201-202). More recently, see M. Inglese, *Regulating the Collaborative Economy in the European Union Digital Single Market*, Springer, 2019; G. Di Federico, *Il ruolo del Parlamento Europeo nella costruzione del mercato unico digitale*, in *Alla riscoperta del Parlamento Europeo. 1979-2019*, Torino, 2021, p. 71 ss.; L. Dabrowsky, M. Suska, *The European Digital Single Market: Europe Digital Transformation*, London, 2022; F. Ferri, *Il bilanciamento dei diritti fondamentali nel mercato unico digitale*, Torino, 2022; F. Ferretti, *Consumers in the Digital Single Market*, in *European Business Law Review*, 2022, p. 477 ss.

74. B. Nascimbene, *Il Mercato Unico Digitale quale nuova frontiera dell'integrazione europea: considerazioni introduttive*, in F. Rossi Dal Pozzo (a cura di), *Mercato Unico Digitale, dati personali e diritti fondamentali*, Milano, 2020, p. 11.

75. *Ivi*, p. 12.

76. See D. Adamski, *Lost on the digital platform: Europe's legal travails with the digital Single Market*, in *Common Market Law Review*, 2018, p. 719.

77. *Ivi*, p. 721.

78. E. Pedilarco, *Il mercato unico digitale per l'integrazione europea. La prospettiva del Fintech*, in *Rivista del diritto dei media. Media Law*, 2018, p. 444.

79. *Ibidem*.

Therefore, the Digital Single Market Strategy for Europe is the EU's first concrete response to the challenges posed by the new digital economy.

Information and communication technologies have become the foundation of all modern innovative economic systems⁸⁰.

Within this changing context, the Strategy is based on three fundamental pillars.

The first is dedicated to “better access for consumers and businesses to online goods and services across Europe”, which requires the rapid removal of key differences between the online and offline worlds to break down barriers to cross-border online activity. The second pillar is related to “creating the right conditions for digital networks and services to flourish”, which requires high-speed, secure, and trustworthy infrastructure and content services. The third pillar involves “maximizing the growth potential of our European Digital Economy”, which requires investment in ICT infrastructure and technologies such as cloud computing and big data and research and innovation to boost industrial competitiveness and better public services⁸¹.

All the pillars are underpinned by a radical and innovative reform of the traditional regulatory legal system, which appears unable to withstand the disruptive impact of the new digitalization.

The various changes brought about by technological innovations also impact the world of law, forcing an almost radical review of obsolete conceptual categories and legal institutions^{82,83}.

On this point in particular, the first of the three pillars eliminates the fundamental differences that separate the online world from the offline world to break down the legal and economic barriers that block online activities across borders, which implies the need to build a new legal regulation for cross-border e-commerce.

One reason “consumers and smaller companies do not engage more in cross-border e-commerce is because the rules that apply to these transactions can be complex, unclear and may differ between Member States. Having 28 different national consumer protection and contract laws discourages companies from

80. M.C. Fregni, *Mercato Unico Digitale e tassazione: misure attuali e progetti di riforma*, in *Rivista di diritto finanziario e scienza delle finanze*, 2017, p. 53.

81. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, A Digital Single Market Strategy for Europe, n. 192, 6 May 2015, pp. 3-4.

82. M.C. Fregni, *Mercato Unico Digitale e tassazione: misure attuali e progetti di riforma*, p. 55.

83. G. Caggiano, *Il quadro normativo del Mercato Unico Digitale*, in F. Rossi Dal Pozzo (a cura di), *Mercato Unico Digitale, dati personali e diritti fondamentali*, Milano, 2020, p. 13.

cross-border trading and prevents consumers from benefiting from the most competitive offers and from the full range of online offers”⁸⁴.

On this point, the “EU consumers could save EUR 11.7 billion each year if they could choose from a full range of EU goods and services when shopping online”; moreover, “61% of EU consumers feel confident about purchasing via the Internet from a retailer located in their own Member State, while only 38% feel confident about purchasing from another EU Member State”: furthermore, “Only 7% of SMEs in the EU sell cross-border. In a Single Market, companies should be able to manage their sales under a common set of rules. Some aspects of consumer and contract law have already been fully harmonized for online sales (such as the information that should be provided to consumers before they enter a contract or the rules governing their right to withdraw from the deal if they have second thoughts). However, other aspects of the contract (such as what remedies are available if tangible goods do not conform to the contract of sale) are only subject to EU rules providing minimum harmonization, with Member States possibly going further. When it comes to remedies for defective digital content purchased online (such as e-books), no specific EU rules exist, and only a few national ones exist. Simplified and modern rules for online and digital cross-border purchases will encourage more businesses to sell online across borders and increase consumer confidence in cross-border e-commerce. If the same rules for e-commerce were applied in all EU Member States, 57% of companies say they would either start or increase their online sales to other EU Member States”⁸⁵.

Among other things, the first pillar focuses on the ban of unjustified geoblocking⁸⁶, which is a practice “used for commercial reasons by online sellers that result in the denial of access to websites based in other Member States”, so “Sometimes consumers are able to access the website but still cannot purchase products or services from it. The consumer may also be re-routed to a local website of the same company with different prices or a different product or service. In other cases, where the sale is not denied, geo-localizing

84. Ivi, p. 4.

85. *Ibidem*.

86. Geoblocking is the ban used by suppliers on web services to limit access to content based on the country you are accessing the services from. The doctrine on this subject is vast; see J. Quinn, *Geo-location technology: restricting access to online content without illegitimate extraterritorial effects*, in *International Data Privacy Law*, 2021, p. 294 ss.; V. Falce, *Appunti sul regolamento europeo sul geo-blocking e la neutralità geografica. In cammino verso il mercato unico digitale*, in *Contratto Impresa*, 2019, p. 1287 ss.; E. Pedilarco, *Il mercato unico digitale per l'integrazione europea. La prospettiva del Fintech*, p. 445 ss., and J. Hoffman, *Crossing borders in the digital market: A proposal to end copyright territoriality and geo-blocking in the European Union*, in *The George Washington International Law Review*, 2017, p. 143 ss.

practices are used, because of which different prices are automatically applied based on geographic location. For example, when online car rental customers in one Member State pay more for an identical car rental in a given destination than online customers in another Member State. Geoblocking is one of several tools companies use to segment markets along national borders (territorial restrictions). By limiting consumer opportunities and choices, geoblocking is a significant cause of consumer dissatisfaction and fragmentation of the Internal Market. The 74% of the complaints received by the European Consumer Centers Network regarding price differences or other geographical discrimination faced by consumers related to online cross-border purchases⁸⁷.

In this sense, “Geoblocking practices may be the result of a unilateral decision by market players, of agreements among competitors to share the market, or of vertical agreements (for distribution rights on a territory). Sometimes these restrictions on supply and ensuing price differentiation can be justified, for instance, where the seller needs to comply with specific legal obligations. However, in many cases, online geoblocking is not justified. These unjustified practices should be expressly prohibited so that EU consumers and businesses can take full advantage of the single market in terms of choice and lower prices. The Commission will make legislative proposals in the first half of 2016 to end unjustified geoblocking. [An] action could include [a] targeted change to the e-commerce framework and the framework set out by Article 20 of the Services Directive. The Commission is also launching a Competition Sector Inquiry focusing on the application of competition law in the e-commerce area⁸⁸.”

On the legality of geographic blocks, legal doctrine has emphasized the negativity assigned to so-called geoblocking. In addition to being seen as an obstacle to the single market, geoblocking can potentially impede the effective and optimal development of e-commerce⁸⁹.

The second pillar of the Single Digital Market Strategy relates to “creating the

87. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, A Digital Single Market Strategy for Europe, n. 192, 6 May 2015, p. 6.

88. *Ibidem*.

89. M.L. Bixio, *La rimozione dei blocchi geografici nel mercato unico digitale, prospettive critiche per la tutela dei diritti d'autore*, in *Il diritto d'autore*, 2019, pp. 1-2, with extensive bibliographical references to which we refer. The author also refers to the significant results of a survey conducted by the European Commission, Geoblocking of Consumers On line: Findings of a mystery shopping carried out by the European Commission”, from which it emerges that out of the 10.537 e-commerce platforms consulted in the survey, the majority (68%) of online digital content suppliers said they applied geoblocking to users residing in other EU member states. In general, geoblocking is applied after analyzing the Internet Protocol of the user, which makes it possible to identify and geolocate the computer or device connected to the service (p. 16, note 3).

right conditions for digital networks and services to flourish” and aims to boost digital innovation and economic growth. This pillar highlights how the Digital Single Market “must be built on reliable, trustworthy, high-speed, affordable networks, and services that safeguard consumers’ fundamental rights to privacy and personal data protection while encouraging innovation. This requires a strong, competitive, and dynamic telecoms sector to make the necessary investments to exploit innovations such as cloud computing, big data tools, or the Internet of Things. The market power of some online platforms potentially raises concerns, particularly concerning the most powerful platforms whose importance for other market participants is becoming increasingly critical”⁹⁰.

The elaboration of a single definition of an online platform is difficult due to continuous evolution⁹¹.

Nevertheless, the Communication assumes a decisive and mature approach toward the role of such platforms (e.g., search engines, social media, e-commerce platforms, app stores, and price comparison websites).

They emphasize how they “are playing an ever more central role in social and economic life: they enable consumers to find online information and businesses to exploit the advantages of e-commerce. Europe has a strong potential in this area but is held back by fragmented markets, which make it hard for businesses to scale up”⁹².

Remember, “Platforms generate, accumulate, and control an enormous amount of data about their customers and use algorithms to turn this into usable information. The growth of such data is exponential; 90% of all data circulating on the Internet were created less than 2 years ago. Moreover, platforms have proven to be innovators in the digital economy, helping smaller businesses to move online and reach new markets. New platforms in mobility services, tourism, music, audiovisual, education, finance, accommodation, and recruitment have rapidly and profoundly challenged traditional business models and have grown exponentially. The rise of the sharing economy also offers opportunities for increased efficiency, growth, and jobs, through improved consumer choice, but also potentially raises new regulatory questions”⁹³.

Furthermore, due to the enormous power wielded by some of these platforms, highlighting that “some platforms can control access to online markets and

90. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, A Digital Single Market Strategy for Europe, n. 192, 6 May 2015, p. 6.

91. G. Caggiano, *Il quadro normativo del Mercato Unico Digitale*, in F. Rossi Dal Pozzo (a cura di), *Mercato Unico Digitale, dati personali e diritti fondamentali*, p. 13.

92. Ivi, p. 10.

93. Ivi, p. 11.

can exercise significant influence over how various players in the market are remunerated. This has led to a number of concerns over the growing market power of some platforms”: moreover, “These include a lack of transparency as to how they use the information they acquire, their strong bargaining power compared to that of their clients, which may be reflected in their terms and conditions (particularly for SMEs), promotion of their services to the disadvantage of competitors, and non-transparent pricing policies, or restrictions on pricing and sale conditions. These will be addressed in the upcoming Internal Market Strategy and the e-commerce framework. Some online platforms have evolved to become players competing in many sectors of the economy, and how they use their market power raises many issues that warrant further analysis beyond the application of competition law in specific cases”⁹⁴.

The European regulator dedicates the third pillar to “maximizing the growth potential of the digital economy”, stressing that “Within less than a decade, most economic activity will depend on digital ecosystems, integrating digital infrastructure, hardware and software, applications, and data. Digitization of all sectors will be needed if the EU is to maintain its competitiveness, keep a strong industrial base, and manage the transition to a smart industrial and services economy. 75% of the value added by the Digital Economy comes from traditional industries, rather than ICT producers, but the integration of digital technology by businesses is the weakest element. Only 1.7% of EU enterprises make full use of advanced digital technologies, while 41% do not”⁹⁵.

Additionally, “Digitalization also offers unprecedented opportunities to other economic sectors, such as transport (e.g., intelligent transport systems) or energy (e.g., smart grids, metering). The EU needs a range of measures to ensure that European industries are at the forefront of developing and exploiting ICT, automation, sustainable manufacturing, and processing technologies to serve future markets. A digital economy can also make society more inclusive. Citizens and businesses are not currently getting the full benefits from digital services (from e-government, e-health, and e-energy to e-transport) that should be available seamlessly across the EU. The Commission will inform the social partners and invite them to include the Digital Single Market in their social dialogue at [the] European level [...]. Data are often considered a catalyst for economic growth, innovation, and digitalization across all economic sectors, particularly for SMEs (and startups) and for society as a whole. Big data and High-Performance Computing are also changing the way research is performed and knowledge is shared as part of a transition toward a more efficient and

94. *Ibidem*.

95. Ivi, p. 13.

responsive “Open Science”. The big data sector is growing by 40% per year, seven times faster than the IT market. A fragmented market does not provide sufficient scale for cloud computing, big data, data-driven science, and the Internet of Things to reach their full potential in Europe”⁹⁶.

To fully exploit the growth potential offered by the digital economy, it is necessary to rethink the regulatory framework required to “remove a series of technical and legislative barriers. Restrictions, such as those related to data location (i.e., Member States’ requirements to keep data inside their territory), force service providers to build expensive local infrastructure (data centers) in each region or country. Fragmented implementation of copyright rules and lack of clarity over rights to use data further obstruct the development of cross-border data use and new applications of technologies (e.g., text and data mining). The lack of open and interoperable systems and services and data portability between services represents another barrier to the cross-border flow of data and the development of new services (e.g., multi-modal travel information systems and data-driven science). Legal certainty regarding the allocation of liability (other than personal data-related) is important for the rollout of the Internet of Things. Businesses and consumers still do not feel confident enough to adopt cross-border cloud services for storing or processing data because of concerns relating to security, compliance with fundamental rights, and data protection more generally”⁹⁷.

The relation between the digital economy and society appears significant, emphasizing the need to build an inclusive e-society, stating “[t]he Commission aims to support an inclusive Digital Single Market in which citizens and businesses have the necessary skills and can benefit from interlinked and multi-lingual services, from e-government, e-justice, e-health, e-energy, or e-transport”, where “Demand for digitally skilled employees is growing by around 4% a year. Shortages of ICT professionals in the EU could reach 825,000 unfilled vacancies by 2020 if no decisive action is taken. The EU has seen improvements in the basic digital skills of its citizens (increasing from 55% to 59% of the population) but still has a long way to go. Digital skill levels need also to be raised among employees in all economic sectors and among jobseekers to improve their employability”⁹⁸.

In this context, the Commission strongly reiterates the urgency that “Change is needed in the way education and training systems adapt to the digital revolution”. Furthermore, changes “can draw on EU-level initiatives such as the ‘Grand Coalition for digital jobs’, ‘EU Code Week’, and ‘Opening up

96. Ivi, p. 14.

97. Ivi, p. 13.

98. Ivi, p. 16.

Education””. The same European Commission “will support their efforts and will play its role in enhancing the recognition of digital skills and qualifications and increasing the level of ICT professionalism in Europe”⁹⁹.

The introduction of an innovative European regulatory framework for the Digital Single Market is, therefore, one of the qualifying and strategic points for defining new business opportunities for companies, including smaller ones.

However, this ambitious project needed to be extensively fine-tuned concerning implementation within the European economic reality.

Its formal expression can be found in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions on The Mid-Term Review on the implementation of the Digital Single Market Strategy, A Connected Digital Single Market for All, May 10, 2017, n. 228.

In The Mid-Term Review on the implementation of the Digital Single Market Strategy, the European Commission states how “People and businesses in the EU have the inherent strengths needed to take advantage of the Digital Single Market [...]. These include a strong manufacturing base and a fast-growing startup ecosystem, which, combined with newly digitized industrial processes and a skilled workforce, can quickly drive growth. To fully unlock the data economy, the EU must also harness such assets to maximize the digitization of the European service sectors, particularly health and care, energy, transport, and finance”¹⁰⁰.

To achieve these ambitious objectives, “The completion of the EU Single Digital Market also needs a clear and stable legal environment to stimulate innovation, tackle market fragmentation, and allow all players to tap into the new market dynamics under fair and balanced conditions. This will provide the bedrock of trust essential for business and consumer confidence. This was the goal of the Digital Single Market strategy”¹⁰¹.

Therefore, “In the two years since the adoption of the strategy, the Commission has made proposals on all 16 key measures identified. They focus on areas where the EU can bring specific benefits, concentrating on European digital projects whose scope and scale cannot be realized by individual countries

99. *Ibidem*.

100. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions on The Mid-Term Review on the implementation of the Digital Single Market Strategy, A Connected Digital Single Market for All, 10 May 2017, n. 228, p. 2. Regarding health system see G. Fiorentini, C. Ugolini, *L'analisi economica delle relazioni tra ICT e organizzazioni sanitarie*, in *Salute e Società*, 2017, p. 42 ss.; A. Santuari, *Paradigms of Healthcare Systems, Law, and Regulation: A Transatlantic Conversation*, in *The Oxford Handbook of Comparative Health Law*, Oxford, 2021, p. 1 ss.

101. *Ibidem*.

alone. It is critical for all parties to ensure that the measures are adopted, fully implemented, and effectively enforced in a timeframe coherent with the fast development of a digital economy. The Commission will bring to bear the full range of policy instruments and funding opportunities to help make this happen, but the full support of Member States, the European Parliament, the Council, and stakeholders is essential; otherwise, the Digital Single Market will simply not become a reality”¹⁰².

To benefit from all the advantages of a complete realization of the Digital Single Market, the European regulator highlights the need to strengthen and promote online platforms “as responsible players of fair Internet ecosystem online platforms drive innovation and growth in the digital economy”. Hence, “they play an important role in the development of the online world and create new market opportunities, notably for SMEs. At the same time, platforms have become key gatekeepers of the Internet, intermediating access to information, content, and online trading. Online platforms organize the Internet ‘ecosystem’, and this is a profound transformation of the World Wide Web, bringing new opportunities, but also challenges”¹⁰³.

In fact, “82% of SME respondents to a recent Eurobarometer survey on online platforms rely on search engines to promote products and/or services online; 66% indicate that their position in the search results significantly impacts their sales. Almost half (42%) of SME respondents use online marketplaces to sell their products and services. In addition, 90% of respondents to the Commission’s fact-finding on platform-to-business trading practices use online social media platforms for business purposes. A majority (53%) of respondents to a 2016 Eurobarometer survey said they follow debates on social media, for example, by reading articles online or through online social networks or blogs. Most of those who follow or participate in debates have heard, read, seen, or experienced cases where abuse, hate speech, or threats are directed at journalists/bloggers/people active on social media (75%)”¹⁰⁴.

Then, to favor and ensure a “fair and innovation-friendly platform economy”, the European Commission “has conducted a fact-finding exercise on platform-to-business trading practices. Preliminary results indicate that some online platforms are engaging in trading practices to the potential detriment of their professional users, such as removing (‘delisting’) products or services without due notice or any effective possibility of contesting the platform’s decision. There is widespread concern that some platforms may favor their products or

102. *Ibidem*.

103. *Ivi*, p. 7.

104. *Ibidem*.

services, otherwise discriminate between different suppliers and sellers, and restrict access to and the use of personal and non-personal data, including those directly generated by a company's activities on the platforms"¹⁰⁵.

The European Commission emphasizes how the lack of a legal, regulatory framework even for non-personal data can negatively affect the operations of SMEs, "[w]hereas harmonized rules exist on personal data, access to and re-use of non-personal data in a business-to-business context are dealt with between businesses on a case-by-case, contractual basis. Drawing on the public consultation following the Communication on Building a European Data Economy, the Commission is assessing whether the lack of a clear framework for access to non-personal data stifles innovation and growth, particularly for SMEs, and whether initiatives are needed to foster fair and balanced access to, and use of, data. The Commission's work on access to and use of data will include looking at freeing up further public and publicly funded data, as this is an important source of data for innovative services and scientific research. It will additionally look at the access, under clearly defined conditions, of privately held data for public administrations for the execution of their public interest tasks"¹⁰⁶.

Equally, digitalization becomes crucial for startups, as the Commission itself points out, "The process of boosting digital skills must go hand in hand with the uptake of digital technologies by companies of all sizes and industries. This is an opportunity for startups and SMEs to create new and better products and services at a lower cost and with fewer resources, and EU policies are being shaped to help businesses make the most of this. To help European businesses reap the full benefits of digital technology, in April 2016, the Commission adopted a comprehensive strategy on Digitizing European Industry, which included measures to encourage national initiatives on digitizing industry to cooperate and learn from each other"¹⁰⁷.

To reach this objective, "over the next three years, Horizon 2020 plans for an additional EUR 300 million for activities related to digital innovation hubs, which are essential to support local startups and innovation. A

105. Ivi, pp. 7-8, which also highlights how "Lack of transparency, e.g., in ranking or search results, or lack of clarity regarding certain applicable legislation or policies, have also been identified as key issues. A significant proportion of disagreements between professional users and online platforms remain unresolved, which can create important negative impacts on the affected businesses. The general lack of accessible redress that would allow business users to tackle the emerging issues quickly and effectively when they arise also constitutes a key feature in the platform-to-business context, as highlighted by the emerging evidence. In considering how to address these potential concerns, the Commission's overall policy objective is to safeguard a fair, predictable, sustainable, and ultimately trusted business environment in the online economy".

106. Ivi, p. 11.

107. Ivi, p. 15.

continued investment of nearly EUR 3.2 billion in key technologies, including nanoelectronics, photonics, robotics, 5G, high-performance computing, big data, cloud computing, and artificial intelligence and their integration along the value chains with pilot lines and testbeds, is also planned. Of this investment, EUR 300 million has been specifically planned for developing the next generation of digital industrial platforms, particularly through new reference architecture models leading to smart factories and services. A key success factor to the digitalization of the EU industry is to mobilize a critical mass of investments through leveraging the total European R&I investment by further private and national public investments, notably through Public-Private Partnerships to increase the impact of EU funds on all sectors of the economy. This brings the total European R&I to around EUR 5.5 billion, which will be further leveraged by private and national public investments, notably through Public-Private Partnerships to increase the impact on all sectors of the economy”¹⁰⁸.

However, the disruption caused by digitalization in the industrial sector also touches on the complex issue of financing small businesses, when new FinTech technologies¹⁰⁹ “can improve businesses’ access to finance, reinforce competitiveness, produce consumer benefits, and stimulate the growth of startups”. A public consultation and “blockchain is also one of the breakthrough technologies that can have a huge potential impact in the financial sector, but also far beyond. A European observatory on Blockchain technologies is planned to map and monitor developments, build expertise, and promote use cases. Across all industrial and services sectors, ICT standards, particularly open standards, play an important role in digitization by ensuring interoperability, lowering market barriers, and promoting innovation. Promoting these standards

108. *Ibidem*.

109. Regarding Fintech, the doctrine is ample: see M. Folwarski, *The FinTech Sector and Aspects on the Financial Inclusion of Society in EU Countries*, in *European Research Studies Journal*, 2021, p. 459 ss.; E. Brown, D. Piroška, *Governing Fintech and Intech as Governance: The Regulatory Sandbox, Risk washing and Disruptive Social Classification*, in *New Political Economy*, 2022, p. 19 ss. Regarding this study, see L. Lerong, *Promoting SME Finance in the Context of the Fintech Revolution: A Case Study of the UK’s Practice and Regulation*, in *King’s Research Portal*, 2021, p. 317 ss.; K. Abbasi, A. Alam, M.A. Du, T. Huynh, *FinTech, SME efficiency, and national culture: evidence from OECD Countries*, in *Technological Forecasting and Social Change*, 2021. Moreover, see Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, *On a Digital Finance Strategy for the EU*, 24 September 2020, n. 591, which, after underlining that “The digital transformation of the economy has changed innovation and business models including in financial services” (p. 2), affirms that “Embracing digital finance would unleash innovation and create opportunities to develop better financial products for consumers, including for people currently unable to access financial services. It unlocks new ways of channelling funding to EU businesses, particularly SMEs” (p. 3).

worldwide helps ensure European influence in the globalized economy beyond the single market”¹¹⁰.

A platform economy is a vital tool for small businesses to market products and services and access the financing market; however, the Mid-Term Review on the implementation of the Digital Single Market Strategy is also concerned with focusing on the central role played by public entities in the provision of services to all businesses. The critical factor is, as stated in the previous section, the pressing need to modernize the public administration of the individual member states.

4. A new orthogonal axis for the European industry. The Twin Transition and An SME Strategy for a Sustainable and Digital Europe

The recent economic, financial, health, and geopolitical events that have shaken the manufacturing sector have renewed the awareness on the part of European policymakers and regulators of the centrality of the industrial sector as a privileged location for experimenting with digital innovations.

At the same time, it is clear that the two significant challenges of the future, the digital revolution and the climate revolution, can only be confronted by new models of capitalism, the market, and business and a new way of running industries.

In this unprecedented scenario, as mentioned above, the environmental, social, and governance (ESG) targets from the United Nations (UN) represent the goals toward which all public and private actors aspire.

Companies of all sizes must rethink every industrial and financial investment from a fundamentally new perspective that is no longer just focused on profit.

Alongside these indications, others have been added at the urging of the UN to build fairer and more sustainable markets from an ESG perspective.

This inevitably requires a profound transformation, accentuated today by technological innovations, which it would not be wrong to define as “disruptive”.

These have had a considerable impact on businesses, but even more significantly, they are affecting the new model of capitalism and the very concept of entrepreneurs; however, what does not change is the centrality of the industrial sector to Europe, where the twin green and digital transitions¹¹¹ are propelling the sector to new horizons.

110. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the Mid-Term Review on the implementation of the Digital Single Market Strategy. A Connected Digital Single Market for All, 10 May 2017, n. 228, p. 15.

111. Regarding the green and digital transitions see M. Passalacqua (a cura di), *Diritti e mercati nella transizione economica e digitale. Studi dedicati a Mauro Giusti*, Padova, 2022, p. 469 ss.

The European Green Deal “aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient, and competitive economy where there are no net emissions of greenhouse gases in 2050 and economic growth is decoupled from resource use. Achieving a climate-neutral and circular economy requires the full mobilization of industry”¹¹².

Europe “has always been the home of industry”, and indeed, “For centuries, it has been a pioneer in industrial innovation and has helped improve the way people around the world produce, consume, and do business”¹¹³.

The European industrial sector is now called upon to face the twin ecological and digital transitions that “will affect every part of our economy, society, and industry. They will require new technologies, with investment and innovation to match. They will create new products, services, markets, and business models”, which must necessarily consider the European Green Deal¹¹⁴, recently supplemented by the Net Zero Industry Act¹¹⁵.

112. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, The European Green Deal, n. 640, 19 December 2019, p. 2.

113. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, A new industrial strategy for Europe, 10 March 2020, n. 102, p. 1.

114. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, The European Green Deal, n. 640, 11 December 2019. Among the various acts related to the European Green Deal, see also Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, Sustainable Europe Investment Plan. European Green Deal Investment Plan, 14 January 2020, n. 21; Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, 27 May 2020, n. 456, Europe’s moment: repair and prepare for the Next Generation; Regulation 2021/241, 12 February 2021, establishing the Recovery and Resilience Facility; Regulation 2021/1056, 24 June 2021, establishing the Just Transition Fund; Regulation 2021/1119, 30 June 2021, establishing The framework for achieving climate neutrality. More recently, see A. Bongardt, F. Torres, *The European Green Deal: more than an Exit Strategy to the pandemic Crisis, a building block of a Sustainable European Economic Model*, in *Journal of Common Market Studies*, 2022, p. 170 ss.; D. Milek, P. Nowak, J. Latosinska, *The Development of Renewable Energy Sources in the European Union in the light of the European Green Deal*, in *Energie*, 2022, p. 1 ss.; S. Rohit, A. Lopes de Sousa Jabbour, J. Vranda, *The Role of Digital Technologies to unleash green recovery: pathways and pitfalls to achieve the European Green Deal*, in *Journal of Enterprise Information Management*, 2022, p. 266 ss.; B. Bertarini, *Il finanziamento pubblico e privato dell’European Green Deal: la tassonomia delle attività economicamente ecosostenibili e la proposta di regolamento sugli European Green Bonds*, in *Ambientediritto.it*, 2022, p. 529 ss.

115. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, A Green Deal Industrial Plan for the Net-Zero Age, n. 62, 1 February 2023.

The European Green Deal highlights that “[a]ll EU actions and policies should pull together to help the EU achieve success and just transition toward a sustainable future. The Commission’s better regulation tools provide a solid basis for this. Based on public consultations, identification of the environmental, social, and economic impacts and analyses of how SMEs are affected and innovation fostered or hindered, impact assessments contribute to making efficient policy choices at minimum costs, in line with the objectives of the Green Deal. Evaluations also systematically assess [the] coherence between current legislation and new priorities”¹¹⁶.

The Green Deal is an integral part of the strategy adopted by the European Commission to carry out the UN’s 2030 Agenda and sustainable development goals¹¹⁷ with the awareness that the EU “has already started to modernize and transform the economy with the aim of climate neutrality. Between 1990 and 2018, it reduced greenhouse gas emissions by 23%, while the economy grew by 61%. However, current policies will only reduce greenhouse gas emissions by 60% by 2050. Much remains to be done, starting with the more ambitious climate action in the coming decade” and “By summer 2020, the Commission will present an impact-assessed plan to increase the EU’s greenhouse gas emission reduction target for 2030 to at least 50% and toward 55% compared with 1990 levels responsibly”¹¹⁸.

The Commission lists several priorities for the industrial sector, aiming primarily to achieve a climate-neutral and circular economy, with 25 years to transform the industrial sector and all the value chains.

The political choice appears irreversible, especially considering that “From 1970 to 2017, the annual global extraction of materials tripled, and it continues to grow, posing a major global risk. About half of the total greenhouse gas emissions and more than 90% of biodiversity loss and water stress come from resource extraction and processing of materials, fuels and food. The EU’s industry has started the shift but still accounts for 20% of the EU’s greenhouse gas emissions. It remains too ‘linear’ and dependent on the throughput of new materials extracted, traded, and processed into goods, finally disposed of as waste or emissions. Only 12% of the materials it uses come from recycling”¹¹⁹.

Therefore, the green transition represents a great opportunity “to expand

116. Ivi, p. 19. See G. de Vergottini, *La tutela dell’ambiente e la Comunità europea*, in *Affari esteri*, 1993, p. 3 ss.

117. United Nations, General Assembly, A/RES/70/1, 21 October 2015.

118. Ivi, p. 4.

119. Ivi, p. 7.

sustainable and job-intensive economic activity. Global markets have significant potential for low-emission technologies, sustainable products, and services. Likewise, the circular economy offers great potential for new activities and jobs. However, the transformation is taking place at too slow a pace, with progress neither widespread nor uniform. The European Green Deal will support and accelerate the EU's industry transition to a sustainable, inclusive growth model"¹²⁰.

It should be emphasized that the twin ecological and digital transitions “will take place in a time of moving geopolitical plates that affect the nature of competition. The need for Europe to affirm its voice, uphold its values, and fight for a level playing field is more important than ever. This is about Europe's sovereignty”, to such an extent that President von der Leyen's Political Guidelines have indicated “the priorities set out by the European Parliament and the European Council's Strategic Agenda 2019-2024. The European Green Deal and the Commission's recent Strategy on Shaping Europe's Digital Future set the ambition, speed, and direction of travel for the years to come”¹²¹.

These actions necessitate “a new industrial way for Europe, fit for the ambitions of today and the realities of tomorrow”¹²². Moreover, “today and tomorrow, the industrial sector is central to Europe's future progress and prosperity. It makes up more than 20% of the EU's economy and employs around 35 million people, with many millions more jobs linked to it at home and abroad. It accounts for 80% of goods exports and is a key reason behind the EU's position as a top global provider and destination for foreign direct investment”. In this context, “Small- and medium-sized businesses (SMEs) account for over 99% of all European firms, the vast majority of which are family-run companies and are our economic and social backbone”¹²³.

Therefore, to make the regulatory legal framework for industry definitive, the Commission saw the need to draw up the Single Market Enforcement Action Plan¹²⁴, designed “to strengthen joint efforts in this area, notably the

120. *Ibidem*.

121. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, A new Industrial Strategy for Europe, 10 March 2020, n. 102, p. 1.

122. *Ibidem*.

123. *Ivi*, p. 2.

124. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, Long Term Action Plan for better implementation and enforcement of Single Market rules, 10 March 2020, n. 94. The Action Plan shows that “A well-functioning single market allows EU citizens to enjoy a wider choice of services and products and better job opportunities. The single market gives EU economic operators a large domestic market,

creation of a Single Market Enforcement Task Force”. This is also highlighted in the Single Market Barriers Report, which “shows the need to break down the barriers facing businesses when selling goods or more acutely when providing services cross-border”¹²⁵.

In other words, “Single market legislation must also be reviewed and updated to ensure that it is fit for the digital age” (included in “the revision of EU rules on product safety, the implementation of the European Data Strategy and the adoption of the Digital Services Act”).

Additionally, an “SME to SME approach” “will also be essential”¹²⁶, as the growing “number of young, tech-savvy SMEs can help more established industrial firms to adapt their business models and develop new forms of work for the digital age. This has already created new opportunities, and startups should be supported to help build the platform economy, new forms of work must come with modern and improved forms of protection, including for those working on online platforms”¹²⁷.

In the future, digitalization will increasingly entail the need to create “an inclusive and open Industrial Forum consisting of representatives from industry, including SMEs, big companies, social partners, researchers, as well as Member States and EU institutions” to create real industrial ecosystems¹²⁸.

The digital future of the economy and European industrial sector is now a reality, and the combination appears to be increasingly inseparable, as highlighted by the Commission in the Communication to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, *Shaping Europe’s Digital Future*, February 19, 2020, n. 67, which stated, “Introduction Digital technologies are profoundly changing our daily life, our way of working and doing business, and how people travel, communicate, and relate. Digital communication, social media interaction, e-commerce, and digital enterprises are steadily transforming our world. They are generating an ever-increasing amount of data, which, if pooled

stimulating trade, and competition, improving efficiency. This is fundamental for achieving the EU’s green and digital transformations and serves as a springboard to compete globally. To make the single market work for all, EU law puts in place common rules to eliminate barriers and facilitate the circulation of goods and services across the EU while also protecting consumers”.

125. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, *A new industrial strategy for Europe*, 10 March 2020, n. 102, p. 5.

126. *Ivi*, p. 6.

127. *Ibidem*.

128. *Ibidem*.

and used, can lead to new means and levels of value creation. It is a fundamental transformation caused by the industrial revolution”¹²⁹.

Thus, digitalization will become the instrument to build a fairer and more competitive economy.

When “In an ever-shrinking world where technology is gaining in importance, Europe needs to continue to act and decide independently and reduce over-reliance on digital solutions created elsewhere. For the development of many products and services, data must be widely and easily available, accessible, and simple to use and process. Data has become a key factor of production, and the value it creates has to be shared with the entire society participating in providing the data. This is why we need to build a genuine European single market for data, a European data space based on European rules and values”¹³⁰.

European enterprises, particularly SMEs, “have been slow at taking up digital solutions, and therefore have not benefited from them and missed opportunities to scale up. The Commission will seek to address this issue with a new EU Industrial Strategy that will set out actions to facilitate the transition toward a more digital, clean, circular and globally competitive EU industry”. This approach includes a “strategy for SMEs, a vital part of the European economy, often hampered by a lack of available skills, access to finance and markets. To start up and grow in Europe, SMEs need a frictionless single market, unhampered by diverging local or national regulations that increase administrative burdens for smaller companies. They need clear and proportionate rules that are effectively and uniformly enforced across the EU, providing them with an immensely powerful home market from which to launch themselves on the world stage”¹³¹.

In this digital context, “ensuring a level playing field for businesses, big and small, is more important than ever. This suggests that offline rules, from the competition and single market rules, consumer protection, to intellectual property, taxation, and workers’ rights, should also apply online”. Therefore, “Consumers need to be able to trust digital products and services just as much as they would any other. There is a need to pay attention to the most vulnerable

129. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, *Shaping Europe’s Digital Future*, 19 February 2020, n. 67, p. 1, observe how a fair and competitive economy is realized by reaching the objective of “A frictionless single market, where companies of all sizes and in any sector can compete on equal terms and can develop, market and use digital technologies, products, and services at a scale that boosts their productivity and global competitiveness, and consumers can be confident that their rights are respected” (p. 2).

130. Ivi, p. 7.

131. Ivi, p. 8.

consumers and to ensure the enforcement of safety laws, also in relation to goods originating from third Countries. Some platforms have acquired significant scale, which effectively allows them to act as private gatekeepers to markets, customers and information”¹³².

Therefore, it is important to ensure “that the systemic role of certain online platforms and the market power they acquire will not put in danger the fairness and openness of our markets. Concerning EU competition law, its foundations are as relevant for digital as for traditional industries”¹³³.

Faced with the sudden and profound changes brought about by digitalization, Europe issued a specific SME Strategy in 2020, An SME Strategy for a Sustainable and Digital Europe, contained in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions on 10 March 2020, n. 103.

The new Strategy is a cornerstone of legal regulation for smaller companies, linking it with the Green Deal and Shaping Europe’s Digital Future.

The Strategy is based on the consideration that “Europe’s 25 million small and medium enterprises (SMEs) are the backbone of the EU economy. They employ around 100 million people, account for more than half of Europe’s GDP, and play a key role in adding value in every sector of the economy”¹³⁴.

In addition, “SMEs are deeply woven into Europe’s economic and social fabric. They provide two out of three jobs, bring training opportunities across regions and sectors, including for low-skilled workers, and support society’s welfare, including in remote and rural areas”. Moreover, “SMEs are very diverse in terms of business models, size, age, and entrepreneurs’ profiles, and draw on a diverse talent pool of women and men”. In fact, SMEs range “from liberal professions and microenterprises in the services sector to middle-range industrial companies, from traditional crafts to high-tech startups”¹³⁵.

Based on this data and elements of evaluation, the present Strategy “recognizes their different needs, helping companies not just to grow and scale up, but also to be competitive, resilient, and sustainable”¹³⁶, emphasizing how “SMEs bring innovative solutions to challenges such as climate change,

132. Ivi, p. 8.

133. *Ibidem*.

134. Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, An SME Strategy for a Sustainable and Digital Europe, 10 March 2020, n. 103, p. 1. At a national level see Gennari F. (a cura di), *Lo sviluppo sostenibile delle micro e medie imprese*, Torino, 2019.

135. *Ibidem*.

136. *Ibidem*.

resource efficiency and social cohesion and help spread this innovation throughout Europe's regions. They are central to the EU's twin transitions to a sustainable and digital economy"¹³⁷.

Moreover, it is precisely the issue of sustainability that is central to the future construction of legal regulation, so much so that the declared objective of this Strategy is "to unleash the power of Europe's SMEs of all kinds to lead the twin transitions. It aims to considerably increase the number of SMEs engaging in sustainable business practices and the number of SMEs employing digital technologies. Ultimately, the goal is that Europe becomes the most attractive place to start a small business, make it grow and scale up in a single market"¹³⁸.

The Strategy developed by the European Commission is based on three fundamental pillars: "Capacity-building and support for the transition to sustainability and digitalization; Reducing regulatory burden and improving market access; and Improving access to financing". In particular, the first underlines how "Competitive sustainability is Europe's guiding principle for the future. Achieving a climate-neutral, resource-efficient and agile digital economy requires the full mobilization of SMEs"¹³⁹.

To make this transition "more economically, environmentally, and socially sustainable, Europe must go hand in hand with the transition to digitalization. For this, tailor-made measures are a prerequisite to develop a thriving SME layer of the economy and giving opportunities for growth to those SMEs that wish to scale up. EU-wide investment is needed to create the appropriate business and innovation infrastructure for SMEs"¹⁴⁰.

It is becoming increasingly evident that "SMEs are driving the sustainable transition. Many SMEs are well-equipped, flexible, high-tech, innovative, and committed to the values driving sustainability and the circular economy. Almost a quarter of SMEs in Europe already enable the transition by offering green products or services, and many SMEs (including social economy enterprises) are already doing a lot for the communities where they are based. There are also major challenges", so it is essential "to support SMEs in this process and equip them with instruments to understand environmental risks and mitigate those covering specific sectors, including construction, plastics, electronics and agro-food"¹⁴¹.

137. *Ibidem*.

138. *Ibidem*.

139. *Ibidem*.

140. Ivi, p. 2.

141. Ivi, p.3.

The Strategy also emphasizes how SMEs are crucial players in the digital transition, from the moment that “Only a thriving community of SMEs using digital technologies and data can position Europe as a world leader in shaping the digital economy. Digitalization can provide great opportunities for SMEs to improve the efficiency of production processes and the ability to innovate products and business models. Using advanced disruptive technologies, such as blockchain and artificial intelligence (AI), cloud and high-performance computing (HPC) can dramatically boost their competitiveness”¹⁴².

Furthermore, “SMEs do not yet fully benefit from data, the lifeblood of the digital economy. Many are unaware of the value of the data they create and are not sufficiently protected or prepared for the upcoming data-agile economy”¹⁴³.

To enable SMEs to benefit from the digital revolution, particularly big data, the European Commission establishes that they “will be supported by a network of up to 240 Digital Innovation Hubs (DIHs), in each region of Europe, underpinned by investment from the Digital Europe Programme and Structural Funds”¹⁴⁴.

DIHs, which we analyze in the next Chapter, are instruments designed to “help companies (especially small- and medium-sized enterprises) to take advantage of digital opportunities. They offer expertise on technologies, testing, skills, business models, finance, market intelligence, and networking”¹⁴⁵.

They “will act as intermediaries between SMEs and universities/training providers at the local level. Incubating activities will assist SMEs in becoming part of data-driven ecosystems”¹⁴⁶.

142. *Ibidem*.

143. Ivi, p. 4, where it is stated that “Only 17% of SMEs have successfully integrated digital technologies into their businesses, compared to 54% of large companies. Traditional SMEs are often uncertain in their choice of digital business strategy, have problems tapping large repositories of data available to larger companies, and shy away from advanced AI-based tools and applications. At the same time, they are very vulnerable to cyber threats”.

144. *Ibidem*.

145. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, Artificial intelligence for Europe, 25 April 2018, n. 237, p. 8.

146. Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, An SME Strategy for a Sustainable and Digital Europe, 10 March 2020, n. 103, p. 6. On this point, see the Communication from the Commission to the European Parliament, the European Council, the European Economic and Social Committee, and the Committee of the Regions, Artificial intelligence for Europe, 25 April 2018, n. 237. These specify, “Europe can only reap the full benefits of AI if it is available and accessible to all. The Commission will facilitate access to all potential users, especially small- and medium-sized enterprises, companies from non-tech sectors, and public administrations, to the latest technologies and encourage them to test AI. To this end, the Commission will support

Regarding DIH, “The ambition is not only to deliver user-friendly and targeted advice on sustainability and digitalization but also to connect support structures so that every SME has advice nearby. The EEN will work closely with DIHs, Startup Europe, and others to ensure a seamless support and advice service, including with national, regional, and local authorities and support structures. The transfer of best practices, know-how, and skills can also happen directly from digital SMEs to SMEs from other fields”¹⁴⁷.

To expedite the twin transitions by SMEs, the Commission has established necessary and numerous organizational measures that seem insufficient if not adequately embedded in a clear, transparent, and business friendly regulatory circuit.

The numerous initiatives indicated by the Commission include strengthening the Enterprise Europe Network “including with dedicated Sustainability Advisors and other sustainability services” and elaborating specific digital crash courses for SME employees “to become proficient in areas such as AI, cybersecurity, or blockchain”. Further initiatives include the Digital Volunteers program “to allow young skilled people and experienced seniors to share their digital competence with traditional businesses” and the updating of the Skills Agenda for Europe, “including a Pact for Skills with a dedicated component for SMEs”. Finally, the Commission suggested strengthening the already mentioned Digital Innovation Hubs and the allocation on the part of the Commission of “at least EUR 300 million to encourage breakthrough Green Deal innovations under the EIC”¹⁴⁸.

Suppose the measures proposed by the Commission are to be truly effective.

In that case, they must be part of a general regulatory framework that is therefore central to the strengthening of the smaller enterprise and is a vital point in the attempt to revise the regulation of smaller enterprises operating in Europe.

the development of an ‘AI-on-demand platform’. This will provide a single access point for all users to relevant AI resources in the EU, including knowledge, data repositories, computing power (cloud and high-performance computing), tools, and algorithms. It will offer services and support potential technology users, analyze the business case behind AI in their specific circumstances, and help them integrate AI solutions into their processes, products, and services. To facilitate access to the platform, an existing network of more than 400 Digital Innovation Hubs will be instrumental. Further Hubs are coming on stream, and a dedicated network of Digital Innovation Hubs focused on AI will be created” (pp. 7-8).

147. Ivi, p. 4, where it states that “As announced in the European Strategy for Data, the Commission will work on the wider accessibility of data and enabling data flows between businesses and governments by establishing common European data spaces for trusted and secure sharing of data. Fair access for all companies, especially SMEs, will be ensured”.

148. Ivi, p. 6.

This issue is well known to the European Commission, on which it bases the second pillar of the Updating the 2020 new Industrial Strategy, entitled Reducing the regulatory burden and improving market access, which emphasizes how regulatory constraints can represent an insurmountable obstacle to conducting business activities, if not adequately controlled¹⁴⁹.

After having specified “The single market is the go-to-market for European SMEs” because “accounts for 70% of the value of SME goods exports, and 80% of all exporting SMEs sell to other Member States”¹⁵⁰.

At the same time, the European Commission, on this point, recalls that “Nevertheless, the number of SMEs exporting to other Member States could be much higher: for example, only 17% of all manufacturing sector SMEs export within the single market. The Single Market Barriers Communication shows that SMEs are most affected by continuing barriers”. In this sense, “complying with regulations, standards, labels, and administrative formalities affects SMEs more than bigger companies due to their limited financial and human resources. For example, in the business services [sector], costs incurred by SMEs when complying with administrative formalities can reach EUR 10,000. Despite progress since the adoption of the Small Business Act, the cumulative impact of regulation remains a major problem for SMEs”¹⁵¹.

For these reasons, the European Commission intends to systematically break down the legal and regulatory barriers that restrict the entrepreneurial action of smaller companies in the market (also concerning large platforms), proposing to monitor existing SME legislation within the REFIT program. However, this check will also be conducted through the new Fit for Future Platform¹⁵² by strengthening the already mentioned One In–One Out principle through the EU SME Envoy, which is tasked with ensuring that the new legislation is “SME-friendly”.

In particular, the EU SME Envoy “will filter EU initiatives, in collaboration with SME stakeholders, to signal to the Commission those that merit close attention from an SME perspective. In this context, the EU SME Envoy will also bring in the national expertise of the SME Envoys network. The ambition

149. On this point, see the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, Updating the 2020 new industrial strategy: building a stronger single market for Europe’s recovery, 5 May 2021, n. 350.

150. Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, An SME Strategy for a Sustainable and Digital Europe, 10 March 2020, n. 103, p. 7.

151. *Ibidem*.

152. Decreed by the European Commission, 11 May 2020, n. 163/03.

is that all future legislation, at European and national levels, is made with the end user in mind, by identifying potential barriers and mitigating them early on in the process, for example, by using digital tools”. Among these, the “Fit for Future Platform provides the SME perspective in identifying the existing legislation that is particularly burdensome for SMEs” and “will suggest the Commission user-friendly solutions that could be considered for complying with the legislation”¹⁵³.

However, what seems most interesting about this Strategy, initiated by the Commission, is the European regulator’s awareness of the need to initiate significant regulatory experimentation procedures. For example, Regulatory Sandboxes (which we also analyze in the next Chapter) can accurately and proactively try to intercept through careful simulations; these are the most innovative legal instruments, enabling even smaller companies to achieve the goals inherent in green and digital transitions.

There is an awareness that “Some very innovative solutions fail to see the light of day because of regulations that might be outdated or poorly adapted for fast-evolving technologies. One way to address this is through regulatory sandboxes. This enables innovative solutions not already foreseen in regulations or guidelines to be live tested with supervisors and regulators if the appropriate conditions are in place, for example, to ensure equal treatment. Regulatory sandboxes provide up-to-date information to regulators and supervisors on and experience with new tech while enabling policy experimentation. Some Member States have already experimented with such sandboxes for innovative financial services”¹⁵⁴.

Finally, “SME-Friendly” legislation can benefit global markets, representing critical business outlets for SMEs.

However, “only 600,000 SMEs employing roughly 6 million people export goods outside the EU”, so in “multilateral and bilateral dialogs, the Commission will promote an SME-friendly environment in third countries through the exchange of good practices with its partners. It will also launch a new information portal to raise awareness of SMEs on trade policies and provide detailed information on customs procedures and formalities for exporting to third countries. SMEs benefit more from rule-based trade opening than large companies, which have more resources for overcoming trade barriers”¹⁵⁵.

153. Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, *An SME Strategy for a sustainable and digital Europe*, 10 March 2020, n. 103, p. 8.

154. *Ivi.*, p. 9.

155. *Ivi.*, p. 12.

Regarding “SME-Friendly” legislation, the White Paper On Artificial Intelligence. An European approach to excellence and trust of February 19, 2020, n. 65, dedicates a specific “Focus on SMEs”.

It reiterates the necessity for SMEs to access and use AI, particularly by using the above-mentioned DIH and AI-on-demand platforms. Such action “should be strengthened further and foster collaboration between SMEs”. Similarly, “The Digital Europe Programme will be instrumental in achieving this”, with the awareness that “all Digital Innovation Hubs should provide support to SMEs to understand and adopt AI; it will be important that at least one innovation hub per Member State has a high degree of specialization in AI”¹⁵⁶.

The effects of SME-friendly regulation could also produce benefits in terms of financing¹⁵⁷, above all digital ones, where “Fintech innovation based on distributed-ledger technology (‘blockchain’) can open new pathways for SMEs to directly engage with investors, either via trustworthy intermediaries or decentralized by themselves. It can enable SMEs to issue crypto assets and digital tokens, for instance, in the form of bonds. These are attractive for investors because they can be immediately traded. This is a way to offer faster, more efficient and cost-effective financing for SMEs”¹⁵⁸.

In this direction and context, “[t]he Commission will facilitate the use of crypto assets and the uptake of digital tokens by SMEs, investors, and intermediaries, in alignment with the EU’s upcoming Digital Finance Strategy” because “in recent years, there has been a considerable decline in SME investment research. The review of the Markets in Financial Instrument Directive that the Commission will carry out in 2020 will look at how to stimulate research coverage on SMEs”.

156. WHITE PAPER On Artificial Intelligence. A European approach to excellence and trust, 19 February 2020, n. 65, p. 7. See also, the Flash Eurobarometer 486 of the European Commission, SMEs. Startup, Scale-ups, and Entrepreneurship, February–March 2020.

157. Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, An SME Strategy for a Sustainable and Digital Europe, 10 March 2020, n. 103, p. 15, it is known that “SMEs face a major finance gap in Europe of EUR 20–35 billion despite substantial support programmes at the EU and national level, and in some Member States, access to finance remains one of the key problems they face. In 2019, 18% of SMEs in the EU did not obtain the full bank loan for which they had planned. This disadvantages SMEs as bank-based finance accounts for roughly 90% of their financing needs. EU banking regulation must provide the foundation for a stable banking system that delivers adequate finance to all businesses. The EU banking package maintained the SME supporting factor and extended it to all loans provided to SMEs. The Commission will ensure that any future financial market legislation takes account of the interests of European SMEs and supports their uninterrupted access to a wide array of financing options”.

158. *Ibidem*.

The recent strengthening of European efforts to define rules for a resilient, green, and digital European market echoes the European Declaration on Digital Rights and Principles for the Digital Decade of January 26, 2022¹⁵⁹.

The Declaration explicitly states, “People are at the center of the digital transformation in the European Union”, thereby confirming the anthropocentric view that must inform the legal regulation of AI in Europe¹⁶⁰.

With the Communication, An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU Single Market, n. 31, February 2, 2022, the European Commission proposes to address the criticism leveled at the European economy’s regulatory standardization, outlining some critical steps to achieve these objectives. These include establishing a new High-Level¹⁶¹ Forum of Representatives of Member States and European standardization organizations from industry, civil society, and academia to advise on questions of future standardization.

Initiating a review process or developing new standards¹⁶² can achieve the objectives of the twin transitions and establishing a European Union Pole of Excellence¹⁶³ for standardization can make the best use of the expertise present at a European level¹⁶⁴.

159. The European Declaration on Digital Rights and Principles for the Digital Decade. The Declaration states that every person should have access to technology that aims to unite by helping create an equal society (Chapter II). Furthermore, all people should enjoy the benefits of artificial intelligence (Chapter III) and have access to a reliable, safe, and secure online environment (Chapters IV and V). Additionally, digital products and services should be designed, used, disposed of, and recycled to minimize their negative environmental and social impacts (Chapter VI). Finally, “This Declaration should also serve as a reference point for businesses and other relevant actors when developing and deploying new technologies. Promoting research and innovation is important in this respect. Special attention should also be given to SMEs and start-ups”. Regarding smaller companies, it is necessary to build a “fair digital environment” that “Everyone should be able to effectively and freely choose which online services to use, based on objective, transparent, easily accessible and reliable information”. Above all, “Everyone should have the possibility to compete fairly and innovate in the digital environment. This should also benefit businesses, including SMEs” (Chapter III).

160. The opinion of the European Economic and Social Committee on exploiting the economic and social opportunities of digitalization and improving the digital transformation of the economy, especially SMEs, focusing on human-centered artificial intelligence and data, 2021, n. 374/02.

161. Communication from the Commission to the European Parliament, the Council, the European economic and social Committee, and the Committee of the Regions, An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU Single Market, n. 31, 2 February 2022, p. 2.

162. *Ibidem*.

163. *Ibidem*.

164. *Ivi*, p. 3.

With this reform, “SMEs are important drivers of innovation and users of standards”, but “their access to standard development processes and standards needs to be improved. Article 6 of Regulation (EU) n. 1025/2012 foresees more SME-friendly conditions (free access to draft standards, access to the activities of national standardization bodies, applying special rates to standards, etc.)”¹⁶⁵.

165. Ivi, p. 4. SME standardization at a European level was defined by the Long-Term Action Plan for better implementation and enforcement of single market rules (Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, Long Term action plan for better implementation and enforcement of single market rules, 10 March 2020, n 94), p. 2, which stated that “Sometimes, it appears that Member States breach agreed on Single Market rules, or create and tolerate obstacles in national law, to create additional protection in their market and derive advantages for national businesses. The possible gains are often very short-term, but the impact on European businesses can be much more damaging, making it far more difficult to scale up on a genuine level playing field and create global leaders, thus skewing the level playing field from within. This disproportionately affects SMEs and startups. Bigger companies have the means to comply with different sets of rules, but SMEs are the first to be penalised by administrative burdens and complexity, especially when crossing borders to conduct business within the Single Market. This is why the single market, and its proper implementation and enforcement, is fundamental to the SME Strategy also adopted today”.

3. Digital innovation: a new regulation for SMEs. Europe in the Industry 5.0 era

SUMMARY: 1. Europe and Industry 5.0: Cultural revolution of industries and markets – 2. E-government as a key factor in constructing an European regulatory framework for SMEs – 3. New tools for digital legal experimentation for regulating smaller enterprises. Innovation facilitators: Digital innovation hubs – 4. Regulatory Sandboxes for SMEs.

1. Europe and Industry 5.0: Cultural revolution of industries and markets

Recent global events with far-reaching consequences have noticeably impacted the manufacturing sector across the world, prompting discussions on the industrial sector's role in terms of humans and the environment.

In an international context marked by the Covid-19 pandemic and geopolitical conflicts, new economic and social demands have arisen that require innovative solutions to meet present and future challenges¹.

To this end, it is crucial to radically rethink industry's role in society in relation to shareholders and public and private stakeholders. Establishing a new cultural approach is, therefore, necessary to place every person at the center of the economic system.

In 2021, the European Commission's Directorate General for Research

1. M. Lamandini, D. Ramos, C. Bosque, *Next Generation EU: its meaning, challenges and link to sustainability*, in *Financial Stability Amidst and Pandemic Crisis: On top of the Wake*, Frankfurt, EBA, 2021, p. 310 ss. At a national level see C. Bottari, B. Vitiello (a cura di), *Il sostegno pubblico all'economia durante la pandemia*, Bologna, 2021; M. Clarich, *Il PNRR tra diritto europeo e nazionale: un tentativo di inquadramento giuridico*, in *Astrid Rassegna*, 2021, p. 11 ss.; A. Papa, *La riforma della pubblica amministrazione: le prospettive del Piano Nazionale di Ripresa e Resilienza*, in *Passaggi costituzionali*, 2021, p.1 ss.; N. Lupo, *Il Piano Nazionale di Ripresa e Resilienza (PNRR) e alcune prospettive di ricerca per i costituzionalisti*, in *Federalismi*, 2022, p. iv ss.; S. Bandini, *Il contributo del rapporto tra pubblica amministrazione e terzo settore per la realizzazione dei programmi del Piano Nazionale di Ripresa e Resilienza (PNRR)*, in *Innovazione e Diritto*, 2022, p. 1 ss.

and Innovation issued a document titled Industry 5.0: Towards a Sustainable, Human-centric and Resilient European Industry, which contained the European Union’s vision for the future of the manufacturing sector.

Before analyzing the principles that characterize Industry 5.0, it is helpful to remember that it “has its roots in the concept of ‘Industry 4.0’, which has been coined in Germany in 2011, as a future project and part of the country’s high-tech strategy to be commonly adopted by business, science and decision-makers”².

Klaus Schwab, founder and executive director of the World Economic Forum, conceptualized “Industry 4.0” based on the new direction taken by German industrial policy as specified in a report released in 2013 at the Hannover Messe. The report identified the investments needed for the German manufacturing sector in the new era³.

Industry 4.0 is linked to the automation of manufacturing systems that began during the industrial revolution and continued with the digital revolution⁴.

It is based on technological change relative to “key technology”⁵ and a combination of technologies applied to all “smart manufacturing”⁶ sectors. It is founded on the integration of various phases of production and on the close relationship between the people involved in the manufacturing cycle. This interoperability is made possible by using digital technologies relative to data, which are the new factors of production⁷.

The central aspect of Industry 4.0 is the sharing of data and information and the applicability of a potentially infinite number of technologies to the production process. Industry 4.0 has had a significant impact on businesses of all sizes, including small and medium enterprises (SMEs)⁸.

2. European Commission, Directorate General for Research and Innovation, Industry 5.0: Towards a sustainable, human-centric and resilient European Industry, 2021, p. 8; it is stated that “in 2013, Acatech (the German Academy of Engineering Sciences) presented a research agenda and implementation recommendations, which were developed at the instigation of the Federal Ministry of Research (BMBF) and based on the ‘National Roadmap Embedded Systems’. It described the impact that the Internet of Things (IoT) was going to have on the organisation of production thanks to a new interplay between humans and machines and a new wave of digital application to manufacturing. Deutsche Bank (2014) suggested that adoption of Industry 4.0 was to become the ‘factory outfitter of the world’”.

3. N. Faraoni, T. Ferraresi, N. Sciclone, *Siamo pronti alla Quarta rivoluzione industriale? Evidenze dal caso italiano*, in *Economia e lavoro*, 2019, pp. 3-4.

4. G. Bandini, *Il capitale umano e l’innovazione: una prospettiva storica*, in *Quaderni di ricerca sull’artigianato*, 2020, p. 20, states that for some scholars (Atkinson and Wu, 2017), it was not a genuine “revolution”.

5. Ivi, p. 21.

6. *Ibidem*.

7. *Ibidem*.

8. Ivi, p. 20, notes, in particular, that human resources must be trained to understand the

Technological changes and innovations also affect corporate systems. Thus, the technological structure does not operate on its own; it is connected to transformations in organizational structures⁹.

While Industry 4.0 focused on digital transformation as a means to optimize industrial production, Industry 5.0 presents a radical shift wherein digital technology has been placed at the service of humankind.

The European Commission proposes a new industrial paradigm that “should not be understood as a chronological continuation of, or an alternative to, the existing Industry 4.0 paradigm. It is the result of a forward-looking exercise, a way of framing how European industry and emerging societal trends and needs will co-exist. As such, Industry 5.0 complements and extends the hallmark features of Industry 4.0. It emphasises aspects that will be deciding factors in placing industry in future European society; these factors are not just economic or technological in nature, but also have important environmental and social dimensions”¹⁰.

Therefore, Industry 5.0 is a technological revolution and, above all, a cultural revolution. Michael Rada first used the term “Industry 5.0” in 2015 while pointing to the need to put people at the center of the industrial world. Therefore, it is no coincidence that in 2016, Keidanren, Japan’s leading business federation, first developed the concept of “Society 5.0”, emphasizing the close connection between industrial revolution and social transformation.

The European Commission’s document mentions how the concepts of Industry 4.0 and Society 5.0 were “presented by Keidanren, Japan’s most important business federation, in 2016. It has subsequently been promoted by the Japanese government. Japan essentially takes the digitalisation and transformation dimensions, mainly situated on the level of individual organisations and parts of society, to a full national transformational strategy, policy and even philosophy”. In this context of the “‘Societies’ concept, the way in which people ensure their livelihood is directly related to the way they build their society. The numbering up to ‘5’ results from a very different and much longer time scale than that of industrial revolutions [...]. Society 5.0 attempts to balance economic development with the resolution of societal and environmental problems. It is not restricted to the manufacturing sector but

processes and exploit digitalization: in this sense, professionals must have planning models integrated with “smart” support systems for solving complex problems in the context of Industry 4.0 (p. 22).

9. A. Nuvolari, *Rivoluzioni industriali e sviluppo economico: uno schema interpretativo basato sui development blocks*, in *Rivista Italiana di Politiche Pubbliche*, 2020, p. 25.

10. European Commission, Directorate General for Research and Innovation, *Industry 5.0: Towards a sustainable, human-centric and resilient European Industry*, 2021, pp. 6-7.

addresses larger social challenges based on the integration of physical and virtual spaces. Society 5.0 is a society in which advanced IT technologies, Internet of Things, robots, artificial intelligence and augmented reality are actively used in everyday life, industry, healthcare and other spheres of activity, not primarily for economic advantage but for the benefit and convenience of each citizen”¹¹.

More recently, Esben H. Østergaard, founder of Universal Robots, used the term Industry 5.0 in 2018, highlighting how it is now essential to primarily focus on individuals while producing technological and digital instrumentation.

The human-centric approach represents one of the three pillars of Industry 5.0; the other two are sustainability and resilience.

Regarding the first pillar, the European Commission states, “a human-centric approach in industry puts core human needs and interests at the heart of the production process. Rather than asking what we can do with new technology, we ask what the technology can do for us. Rather than asking the industry worker to adapt his or her skills to the needs of rapidly evolving technology, we want to use technology to adapt the production process to the needs of the worker, e.g. to guide and train him/her. It also means making sure the use of new technologies does not impinge on workers’ fundamental rights, such as the right to privacy, autonomy and human dignity”¹².

Regarding sustainability, it states, “For industry to respect planetary boundaries, it needs to be sustainable. It needs to develop circular processes that re-use, re-purpose and recycle natural resources, reduce waste and environmental impact. Sustainability means reducing energy consumption and greenhouse emissions, to avoid depletion and degradation of natural resources, to ensure the needs of today’s generations without jeopardising the needs of future generations. Technologies like AI and additive manufacturing can play a large role here, by optimising resource-efficiency and minimising waste”. In contrast, the pillar of resilience “refers to the need to develop a higher degree of robustness in industrial production, arming it better against disruptions and making sure it can provide and support critical infrastructure in times of crisis. Geopolitical shifts and natural crises, such as the Covid-19 pandemic, highlight the fragility of our current approach to globalised production. It should be

11. Ivi, p. 9; it is specified that “the numbering up to ‘5’ results from a very different and much longer time scale than that of industrial revolutions. The first two ‘Societies’ correspond to the pre-industrial periods (until the end of the 18th century) and are respectively related to the hunting/gathering and the agricultural economies. Society 3.0 is an industrial society and corresponds more or less to the period of the first, the second and part of the third industrial revolutions. Society 4.0 is characterized by the dominance of ‘information’, and we can say that it evolved from a highly digitised version of the third industrial revolution, up until today”.

12. Ivi, p. 14.

balanced by developing sufficiently resilient strategic value chains, adaptable production capacity and flexible business processes, especially where value chains serve basic human needs, such as healthcare or security”¹³.

The European Commission explores what Industry 5.0¹⁴ “may look like and how it could make our industries more future-proof, resilient, sustainable and human-centered” and, in particular, “ways in which technological innovation can be deployed to support a better fit and a ‘win-win’ interaction between industry and society, shifting focus from shareholder to stakeholder value”¹⁵.

Here, the concept of Industry 5.0 is complex and articulated from a technological point of view: “Industry 5.0 wants to come to grips with the promises of advanced digitalization, big data and artificial intelligent, while emphasizing the role these technologies can play to address new emergent requirements in the industrial, societal and environmental escape”. This means “using data and AI to increase production flexibility in times of disruption and rendering value chains more robust”¹⁶.

However, Industry 5.0 is characterized above all by the affirmation of a “human-centric” and “socio-centric approach” that the European Union has followed “in several of its key policies”¹⁷, revealing that “in the industrial context, there is still a place for progress regarding the human-centric approach. In order to ensure that both companies and workers benefit from the digital transition, rethinking and redesigning business models is necessary”¹⁸.

13. *Ibidem*.

14. Ivi, p. 5, it is stated that “industry is the single biggest contributor to the European economy, providing jobs and prosperity across the continent. Between 2009 and 2019, industry constantly accounted for around 20% of EU GDP, with manufacturing in particular adding around 14,5% of value to the EU economy”. For an analysis of Industry 5.0, see Y. Zengin, S. Naktiyok, E. Kaygin, O. Kavak, E. Topçuo, *An investigation upon Industry 4.0 and Society 5.0 within the context of Sustainable Development Goals*, in *Sustainability*, 2021, p. 1 ss.; B. Aquilani, M. Piccarozzi, T. Abbate, A. Codini, *The role of open innovation and value co-creation in the challenging transition from Industry 4.0 to Society 5.0: Toward a theoretical framework*, in *Sustainability*, 2020, p. 1 ss.; F. Aslam, W. Aimin, M. Li, K. Ur Rehman, *Innovation in the era of IoT and Industry 5.0: Absolute innovation management*, in *Information*, 2020, p. 1 ss.; K.A. Demir, G. Döven, B. Sezen, *Industry 5.0 and human-robot co-working*, in *Procedia Computer*, 2019, p. 688 ss.; S. Nahavandi, *Industry 5.0 – A human-centric solution*, in *Sustainability*, 2019, p. 1 ss.; V. Özdemir, N. Hekim, *Birth of industry 5.0: Making sense of big data with artificial intelligence, “the internet of things” and next-generation technology policy*, in *Omics*, 2018, p. 65 ss.

15. European Commission, Directorate General for Research and Innovation, *Industry 5.0: Towards a sustainable, human-centric and resilient European Industry*, 2021, p. 6.

16. Ivi, p. 11.

17. Ivi, p. 25.

18. Ivi, p. 26.

From the point of view of sustainability, the Commission observes, “sustainable development has been the heart of European policy for a long time, firmly anchored in the European Treaties”. Furthermore, only “when fully releasing the advantages of an improved corporate image and of savings on energy and material costs, industry will embrace resource efficiency as a natural choice”¹⁹.

Regarding resilience, the Commission states, “by being resilient in its own right, industry can greatly contribute to societal resilience, making sure production is upheld and workers can continue to work”²⁰.

Within this new way of looking at the industrial sector, smaller companies may also find their place. Industry 5.0 mentions SMEs, stating that the definition of Industry 5.0 is based on several other elements.

Apart from the analysis of the fast-paced societal evolutions in Europe and worldwide²¹, the current policy setting at the European level “aims to better frame and steer these ongoing evolutions, in an effort to maximise their benefits for European society, while mitigating the emerging risks they pose”²².

It also includes the adoption of digital technologies in the European industrial sector, which has an important bearing on the concept of industry²³.

The Commission stresses that “Despite claims of digital technology developing exponentially and becoming ever more disruptive in nature, the

19. Ivi, p. 27.

20. Ivi, p. 28.

21. Ivi, p. 10; the Commission observes that “Advanced globalisation has raised global prosperity, but has also increased local inequality, which led to more fragile strategic value chains for critical supplies and infrastructure and has worsened our overuse of natural resources and pollution of the environment. Technological advancement is an important driver behind these changes, which would simply be unimaginable without increased automation, digitalisation and connectivity. To illustrate the quick and sharp increase of the importance of digital technology: in 2009, only one tech company (Microsoft) made the top-10 of publicly traded companies (by market cap); in 2019, the entire top-5 consisted of only tech companies (Microsoft, Amazon, Apple, Alphabet and Facebook). The emergence of increasingly sophisticated artificial intelligence, attracting major investments worldwide, will only solidify and speed up this evolution. For all the good technological innovations have brought, society is now facing the downsides and risks they pose, including threats to our environment, to European values, including democracy itself, and to fundamental rights”.

22. Ivi, p. 11; the Commission specifies that “this is clearly reflected in two top priorities of the current European Commission: the ‘Green Deal’, an encompassing strategy for making Europe climate-neutral by 2050, and a ‘Europe Fit for the Digital Age’, targeting increased technological innovation in Europe, while introducing new and updated rules for technology and the digital economy. The recently published White Paper on a regulation of artificial intelligence, as well as the European Data Strategy, clearly illustrate the importance the European Commission attaches to the societal impact of digital technologies”.

23. Ivi, p. 10.

adoption of digitalisation in European industry seems to be of a more gradual nature. Although specific new technologies may allow for new, disruptive approaches, the large infrastructural investments required for some types of industry and the fragmentation into a multitude of smaller players (lacking digital skills or investment capacity) in other areas, result in the current uptake of digital technologies in European industry being linear rather than exponential, and gradual rather than disruptive”.

In particular, “the technology picture in European industry is very diverse and ranges from state-of-the-art high-tech production lines to small businesses still keeping their client records in a paper-based rolodex”²⁴.

Large and small companies²⁵ will ultimately be the central lever through which the new industrial vision promoted by the European Commission can be realized.

Only through them can the primary new goals of sustainability, resilience, and the centrality of the individual be achieved and firmly established within the European production system.

SMEs and industry, in general, play an increasingly central role in the radical transformation proposed by Industry 5.0.

This fact is also strongly reiterated in the European Commission’s recent economic and societal impact of research and innovation (ESIR) Policy Brief n. 3, Industry 5.0: A Transformative Vision for Europe, issued in 2022, stating, “In such a context – one that calls on all government and civil society elements to drive change – the role of industry is pivotal. Without a profound industrial transformation, it will be impossible for Europe to realize its ambition to become a more resilient, sustainable, circular and regenerative economy while preserving and nurturing its competitiveness at the international level”²⁶.

The new vision of European industry “has very important consequences for the EU industrial strategy writ large. It requires new economic orientations to industry performance, new design for business models, value chains and supply chains, new purpose for digital transformation, new approaches to policymaking in partnership with business and industry, new capabilities and approaches to research and innovation as well as vertical and horizontal coherence by acting at all levels of government and through international standards. It addresses recent knowledge and learnings from the Covid pandemic and the fundamental need

24. Ivi, p. 11.

25. The European Commission, Annual Report on European SMEs 2020/2021, July 2021; it is reported that SMEs account for 99.8% of businesses in the European market.

26. European Commission, ESIR Policy Brief, Industry 5.0: A Transformative Vision for Europe, 2022, p. 4.

to build resilience across value chains and secure people's lives and livelihoods whilst living within planetary boundaries. It proposes a very different set of enabling approaches to Europe's so-called 'twin transition'²⁷.

Therefore, a new conception of industry, which at a more general level is "first and foremost a decisive move away from the neo-liberal capitalism models with a focus on production for profit and 'shareholder primacy', towards a more balanced view of value over time and multi-valent understanding of capital – human and natural as well financial"²⁸.

A decisive change, built on a concept of resilience, is clearly defined as "more than a due diligence for supply chains but an understanding of de-risking through resilience building". Here, resilience "requires a people-planet-prosperity approach that focuses on short-term levers and long-term planning rather than short term profit seeking"²⁹.

Businesses are then called to a "stress testing and applying Environmental Social Governance (ESG) criteria" that "have already shown greater resilience during the recent pandemic, therefore highlighting the potential role ESG can play in de-risking"³⁰.

In the new "circular" economy, digitalization plays a key role. Specifically, "digital Technologies become an ever more central part of the life of people both as citizens and as employees. They also have the potential to significantly improve the comparative advantage of European manufacturing and thereby protect or even re-shore industrial jobs". Therefore, "Europe's industry will be digitalized, or it will cease to exist"³¹.

The Industry 5.0 approach "would offer the timely opportunity to include specific holistic sustainability and resilience targets within Europe's digital roadmap, so digitalization becomes a lever for lowering the carbon and material footprint of Europe's economy and industry within it and shifts to a people and planet-centred approach"³².

27. Ivi, p. 6.

28. Ivi, p. 7; it is emphasized that "Emphasis on returns to shareholders, cherished by the Chicago school of economics since the time of Milton Friedman, is today widely questioned around the world even in the United States where it has dominated markets and market expectations. Even the increasingly popular notion of 'stakeholder capitalism', while recognizing corporate responsibility for ensuring that all relevant interests represented in the firm are catered for, is insufficient to enable a full transition to Industry 5.0".

29. Ivi, p. 7.

30. *Ibidem*.

31. Ivi, p. 11.

32. Ivi, p. 12; it is stated that new technologies play a huge role "in enabling more sustainable and circular economic models, maximising efficiencies, providing greater transparency, new design tools, new forms of business models, new approaches to manufacturing, repair, upgrade,

The ESIR policy brief devotes particular interest to the wide-ranging and important topic of e-government and the consideration that in the new context outlined by Industry 5.0, “Public sector decision-making and processes are out of sync with the speed, uncertainty and transformation imperative”³³.

In fact, in many countries, “there is a significant discrepancy in the pace of change (and sense of urgency?) between, on the one hand, companies, industries and individuals, many of whom are acutely exposed to far-reaching disruption and rapid change, and, on the other hand, large parts of the public sector that for various reasons moves at a much slower speed”. Therefore, “tackling the increasingly urgent and existential challenges we face and seizing the opportunities that arise in times of disruption, critically depend on a better alignment between the public and private sector”. To reach these objectives, it is necessary, among other things, to activate policy processes, including regulatory change, to “focus more on breaking path dependencies – in areas such as behaviour, regulations, incentive structures and policy design – that lock us into old patterns of consumption, production and organization. Policymaking needs greater awareness of how to achieve ‘unlearning’, address lock-ins and overcome inertia of patterns, policies and processes that prevent necessary and desirable change”³⁴.

Equally, “compliance processes need to happen in parallel rather than sequentially. Notably, there is a need for better governance of policy processes facing new, disruptive and system-changing actors and solutions. Currently, the achievement of systemic changes is hampered and discouraged by sequential policy processes (first you get a permit from one government agency, then you need approval from the next government agency, etc.) which are out of sync with the pace of change required to tackle climate change and handle technological changes and competitive pressures”³⁵.

Moreover, “new actors and solutions often have to navigate a multitude of government agencies with different expertise and responsibilities, without anyone in government assuming a responsibility that the overall processes are effective, synergistic and time appropriate”³⁶.

remufacturing, re-use and re-sale to name a few”. In particular, “Drawing on combinations of sensors, distributed ledger, smart contracts, multi-agent AI, automation and robotisation, nanotech and network computing, digital transformation could play a crucial role in offering better choices for citizens to consume and use resources in vastly more sustainable ways while at the same time participating in the creation of new and better forms of economic growth”.

33. Ivi, p. 14.

34. *Ibidem*.

35. Ivi, p. 15.

36. *Ibidem*.

However, the most important aspect “would be to ensure that, when proposing new rules or evaluating old ones, institutions assess their coherence with an ambitious EU agenda for systemic transformation. Simply applying cost-benefit analysis to new rules, or exclusively focusing on reducing regulatory costs would not lead EU institutions to ‘walk the talk’”³⁷.

Furthermore, “When a regulatory alternative reduces compliance costs but jeopardises systemic transformation, it should not be chosen as the best possible option”³⁸.

Thus, the European Commission, appropriately, “has already announced a gradual reorientation of the better regulation agenda towards the sustainable development goals: however, so far this was only partly achieved, and took rather the form of an add-on to previous methods than a transformational practice that leads the EU to measure progress differently, and more meaningfully”. Therefore, “if transformation is to be achieved, then decision-making tools have to coherently follow”³⁹.

Industry 5.0 leads one to consider that “the same applies to new tools associated with better regulation, such as adaptive and experimental regulation, foresight and horizon scanning”. Nonetheless, “future-proofing public policy requires anticipatory governance and regulation (including regulatory sandboxes), foresight-based policymaking (with foresight or ‘future-scoping’ not only aimed at predicting technological development or trends through horizon scanning, but also to proactively ‘shape the future’) and adaptive regulation”⁴⁰.

It is emphasized that “the mainstreaming of these tools in the daily practice of the Commission is still in its infancy and may require additional guidance and investment over the coming years. Moreover, to maximize impact, the development of transition pathways for industrial ecosystems announced with the update of the EU industrial strategy in May 2021 should be reconciled with the EU Industry 5.0 agenda, as well as with the use of horizon scanning techniques”⁴¹.

The ESIR Policy Brief of 2022 also highlights how Industry 5.0 could represent a genuine opportunity for Europe “to reframe the quality of its

37. *Ibidem*.

38. *Ibidem*.

39. Ivi, p. 16.

40. *Ibidem*, see: GCPSE Foresight-Summary.pdf; Anticipatory Innovation Governance. Observatory of Public Sector Innovation ([oecd-opsi.org](https://www.oecd-opsi.org)); Anticipatory Regulation-Nesta; and European Commission, Communication “Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe’s recovery”, 5 May 2021, at ec.europa.eu/info/files/communication-updating-2020newindustrial-strategy-building-stronger-single-market-europes-recovery_en.

41. European Commission, ESIR Policy Brief, Industry 5.0: A Transformative Vision for Europe, 2022, p. 16.

leadership in the world through international cooperation, openness (while at the same time strengthening strategic autonomy in a way which is aligned with SDGs) and leadership in setting standards and norms for new manufacturing, sustainability, ethics and a digital economy/society⁷⁴².

Therefore, the setting up of an Industry Stability Board was proposed, “analogous to the Financial Stability Board, recognizing the scale of systemic, strategic risks facing businesses and industries in Europe and globally from multiple connected shocks and stresses as well [as] transition costs⁷⁴³”.

2. E-government as a key factor in constructing an European regulatory framework for SMEs

The modernization of public administration has been a central issue for the European Union and its Member States.

Therefore, European regulators stress the need for a good working relationship between public administration and businesses, which digital technologies can strengthen and improve.

The European Commission states, “the digital world is by definition a fast-moving environment where policy needs to adapt to changing circumstances. As new technologies become mainstream, they can bring profound benefits to the economy and to our daily lives. However, it is essential that they be grounded in a set of rules to provide confidence to consumers and business alike⁷⁴⁴”.

In this context, “online platforms drive innovation and growth in the digital economy. They play an important role in the development of the online world and create new market opportunities, notably for SMEs. At the same time, platforms have become key gatekeepers of the internet, intermediating access to information, content and online trading. Online platforms organize the internet ‘ecosystem’ and this is a profound transformation of the World Wide Web, bringing new opportunities, but also challenges⁷⁴⁵”.

The “platform economy⁷⁴⁶” has become a critical strategic instrument for

42. Ivi, p. 22.

43. Ivi, p. 23.

44. 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 the Mid-Term Review on the implementation of the Digital Single Market Strategy. A Connected Digital Single Market for All, 10 May 2017, n. 228, p. 7.

45. *Ibidem*.

46. Regarding the platform economy and regulation, see: P. Falletta, *La trasparenza amministrativa in rete: le nuove piattaforme digitali per la diffusione di contenuti informativi*, in

SMEs to commercialize products and services in a highly competitive context, but it presents standardizing and regulatory obstacles.

Digital technologies allow the private and public sectors to provide efficient, transparent, and prompt services.

The fourth principle of the 2008 Small Business Act for Europe⁴⁷ emphasized the need to “Make public administrations responsive to SMEs’ needs” precisely because “Modern and responsive public administrations can make a major contribution to the success and growth of SMEs by saving them time and money and hence freeing resources for innovation and job creation. E-government and one-stop shops, in particular, have the potential to help improve service and reduce costs. The ongoing implementation process of the Services Directive will contribute to making life easier for SMEs and requires Member States to set up points of single contact, to reduce in number and lighten authorisation schemes, and to eliminate regulatory barriers to the development of service activities. It also offers opportunities to go beyond its requirements in accelerating the start-up of business operations”⁴⁸.

Rivista trimestrale di diritto pubblico, 2021, p. 559 ss.; L. Ammannati, A. Canepa, G.L. Greco, U. Minneci (a cura di), *Algoritmi, Big Data, piattaforme digitali. La regolazione dei mercati in trasformazione*, Torino, 2021; M. Midiri, *Le piattaforme e il potere dei dati (Facebook non passa il Reno)*, in *Il Diritto dell’informazione e dell’informatica*, 2021, p. 111 ss.; M.C. Causarano, *Le piattaforme “online” e la tutela degli utenti digitali al tempo della pandemia*, in *Persona e Mercato*, 2020, p. 466 ss.; F. Koen, A. Van Waes, P. Pelzer, M. Smink, R. Van Est, *Safeguarding public interests in the platform economy*, in *Policy and Internet*; 2020, p. 400 ss.; O. Lukianenko, A. Niameshchuk, *Development of the platform economy in the global digital environment*, in *International Economic Policy*, 2020, p. 26 ss.; R. Petruso, *Osservazioni su contratti algoritmi e tutela del consumatore nell’economia di piattaforma*, in *Annuario di diritto comparato e di studi legislativi*, 2020, p. 139 ss.; G. Pitruzzella, *Riflessioni sul mutamento del diritto della concorrenza nell’economia delle piattaforme e dei “Big Data”*, in *Annuario di diritto comparato e di studi legislativi*, 2020, p. 161 ss.; S.K. Sasikumar, S. Kanikka, *Digital platform economy: Overview, emerging trends and policy*, in *Perspectives Productivity*, 2020, p. 336 ss.; S. Diamond, N. Drury, A. Lipp, A. Marshall, S. Ramamurthy, *The future of banking in the platform economy*, in *Strategy & Leadership*, 2019, p. 34 ss.; M. Dufva, R. Koivisto, L. Ilmola-Sheppard, S. Junno, *Anticipating alternative futures for the platform economy*, in *Technology Innovation Management Review*, 2017, p. 6 ss.; D. McKee, *The platform economy: Natural, neutral, consensual and efficient?*, in *Transnational Legal Theory*, 2017, p. 455 ss.; M. Kenney, J. Zysman, *The rise of the platform economy*, in *Issues in Science and Technology*, 2016, p. 61 ss.

47. European Commission, Communication from the Commission to the Council, the European Parliament, from the Commission, the European Economic and Social Committee and the Regions, “Think Small First”, A “Small Business Act” for Europe, 25 June 2008, n. 394.

48. Ivi, p. 9. To translate this principle into practice, Member States are invited to “reduce the level of fees requested by the Member States’ administrations for registering a business, taking inspiration from EU best performers”; “continue to work to reduce the time required to set up a business to less than one week, where this has not yet been achieved”; “accelerate the start of SMEs’ commercial operations by reducing and simplifying business licences and permits.

The construction of a new regulatory legal system becomes central. The European Commission emphasizes that every public administration must intensify its efforts in listening to and understanding the real needs of smaller companies, particularly by increasing “the use of e-government solutions”⁴⁹.

Furthermore, “the e-Government Action Plan sets out a wide range of actions which will allow SMEs to spend less time on administrative procedures, including through promoting cross-border e-procurement”⁵⁰.

The Commission emphasizes that the “Think Small First” principle should be applied to administrative procedures. This is the central part of the Small Business Act of 2008, which in the 2011 review of the Commission refers to administrative procedures and the regulatory system for smaller companies.

The European Commission “will also work with Member States to further develop the ‘Points of Single Contact’, aimed at considerably facilitating such procedures, into user-friendly e-government portals which allow for electronic completion, including cross-border, of all necessary administrative requirements”⁵¹.

The mid-term review proposed to extend the use of digital instruments to public administration systems using the models and solutions of e-government⁵².

More specifically, Member States could set a maximum deadline of 1 month for granting these licences and permits, except in cases justified by serious risks to people or the environment”; “refrain from asking SMEs for information which is already available within the administration, unless it needs to be updated”; “make sure that a micro-business is not asked to participate in a statistical survey under the responsibility of the state, regional or local statistical office more than once every three years, provided that the needs for statistical and other types of information do not require otherwise”; “establish a contact point to which stakeholders can communicate rules or procedures which are considered to be disproportionate and/or unnecessarily hinder SME activities”; and “ensure full and timely implementation of the Services Directive, including the setting up of points of single contact, through which businesses can obtain all relevant information and complete all necessary procedures and formalities by electronic means”.

49. European Commission, Communication from the Commission to the European Parliament, the Council, Economic and Social Committee and the Committee of the Regions, Review of the “Small Business Act” for Europe, 23 February 2011, n. 78, p. 7.

50. *Ibidem*.

51. *Ibidem*.

52. On this point, 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, EU eGovernment Action Plan 2016-2020. Accelerating the Digital Transformation of Government, 19 April 2016, n. 179; The legal doctrine on the subject of e-government is ample; in particular, see L. Sciannella, “E-government” e accessibilità ai servizi: il “Single Digital Gateway”, in *Ambientediritto.it*, 2021, p. 458 ss.; G. Sgueo, *Tre idee di “design” per l’amministrazione digitale*, in *Giornale di diritto amministrativo*, 2021, p. 19 ss.; G. Sgueo, *La democrazia digitale*, in *Giornale di diritto amministrativo*, 2021, p. 262 ss.; A. Francini, *La digitalizzazione della Pubblica Amministrazione: disamina della normativa*

The European Commission also introduced specific measures aimed at simplifying administrative procedures, including “digital-by-default”⁵³, “once-only”⁵⁴, and the creation of a “single digital gateway”⁵⁵.

tra disciplina eurounitaria e nazionale, in Innovazione e Diritto, 2020, p. 55 ss.; D. Fuschi, Accesso telematico e utilizzo dei dati nell’“e-Government”, in Diritto pubblico comparato ed europeo, 2020, p. 973 ss.; P. Piras, Il tortuoso cammino verso un’amministrazione nativa digitale, in Il Diritto dell’informazione e dell’informatica, 2020, p. 43 ss.; F. Faini, Il volto dell’amministrazione digitale nel quadro della rinnovata fisionomia dei diritti in rete, in Il Diritto dell’informazione e dell’informatica, 2019, p. 1099 ss.; R. Titomanlio, L’amministrazione digitale: norme costituzionali e principi organizzativi, in GiustAmm.it.: norme costituzionali e principi organizzativi, in GiustAmm.it, 2019, p. 1 ss.; B. Carotti, Il correttivo al Codice dell’amministrazione digitale: una meta-riforma Commento a d.lg. 13 dicembre 2017, n. 217, in Giornale di diritto amministrativo, 2018, p. 131 ss.; P. Colitti, La digitalizzazione della Pubblica Amministrazione tra innovazioni tecniche, riforme legislative e piena realizzazione dell’archiviazione digitale, in Rivista Amministrativa della Repubblica Italiana, 2018, p. 641 ss.; E. De Giovanni, Il codice dell’Amministrazione digitale: genesi, evoluzione, principi costituzionali e linee generali, in Rassegna dell’Avvocatura dello Stato, 2018, p. 155 ss.; D.U. Galetta, La Pubblica Amministrazione nell’era delle ICT: sportello digitale unico e intelligenza artificiale al servizio della trasparenza e dei cittadini?, in Ciberspazio e Diritto, 2018, p. 319 ss.; F. Zhao, J. Wallis, M. Singh, E-government development and the digital economy: A reciprocal relationship, in Internet Research, 2015 p. 734 ss.; C. Baitini, Un’introduzione ai servizi di “e-government”, in Amministrare, 2013, p. 37 ss.; D. Arduini, F. Belotti, M. Denni, G. Giungato, L’innovazione nelle Amministrazioni Pubbliche. Evidenza sulla diffusione dell’eGovernment in Italia, in Economia e politica industriale, 2008, p. 173. L. Sciannella, “E-government” e accessibilità ai servizi: il “Single Digital Gateway”, in Ambienteditto.it, 2021, p. 459; it is highlighted that “an assumption that seems particularly pertinent to spending in the ICT field and to spending toward the digitalization of public administration. This will enable the state to not only improve budgetary efficiency but also to transform the very architecture of public policy in the medium to long term, in making it more accessible and less financially burdensome. In fact, digitalization moves administration toward a platform dimension, on which citizens and public services interact; this entails a necessary and parallel transformation of the current organizational models to which is linked a radical rethinking of the way in which data flows are managed”.

53. 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 the Mid-Term Review on the implementation of the Digital Single Market Strategy. A Connected Digital Single Market for All, 10 May 2017, n. 228, p. 17; “digital-by-default” is defined as “providing public services by digital means as the preferred option. This can be facilitated by using eIDAS, eInvoicing and eProcurement services, and their related technical building blocks developed under the Connecting Europe Facility”.

54. *Ibidem*; a one-off process “avoids citizens and companies having to submit the same information to public authorities repeatedly. A Large-Scale Pilot (funded under Horizon 2020) to test the application of the once-only principle for businesses in the EU started in January 2017 with the participation of 21 countries (20 Member States) and more than 50 Organisations (TOOP, ‘The Once-Only Principle’, www.toop.eu). A Coordination and Support Action (funded under Horizon 2020) was launched in November 2016 to discuss the possible application of the once-only principle for citizens in the EU”.

55. *Ibidem*.

The single digital gateway “will help people and businesses to face fewer administrative burdens when moving and/or doing business across borders in the Single Market. It will offer easy access to relevant information and assistance services, it will enable users to complete certain key administrative procedures, online and guarantee non-discriminatory access to national online procedures for users from other countries. It will also set the first step towards implementing the once-only principle in cross-border scenarios”⁵⁶.

The single digital gateway was specially defined by the “Regulation (EU) 2018/1724 of 2 October 2018”, where Article 1 sets out rules “for: (a) the establishment and operation of a single digital gateway to provide citizens and businesses with easy access to high quality information, to efficient procedures and to effective assistance and problem-solving services with regard to Union and national rules applicable to citizens and businesses exercising or intending to exercise their rights derived from Union law in the field of the internal market”; “(b) the use of procedures by cross-border users and the implementation of the ‘once-only’ principle”; and “(c) the reporting on obstacles in the internal market based on the collection of user feedback and statistics from the services covered by the gateway”⁵⁷.

Further, “the regulatory environment must be designed to support individuals and creators in the online environment as much as they are in the offline environment. This is how the EU can become the global norm setter for personal data protection, cybersecurity, net neutrality, and fairness and responsibility in the platform economy”⁵⁸.

However, “having the regulatory framework in place will not by itself make the EU a leader in the digital economy. For that to happen European governments and businesses – large and small – need to invest into and exploit the vast opportunities provided by technologies like Artificial Intelligence and big data and to use the Digital Single Market as the launchpad for deploying competitive solutions for the global data economy”⁵⁹.

In this study, the strengthening e-government measures is of particular

56. *Ibidem*.

57. Article 1,1, Regulation (EU) 2018/1724 of 2 October 2018, establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) n. 1024/2012.

58. European Commission, Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Completing a trusted digital single market for All. The European Commission’s contribution to the informal EU Leaders’ meeting on data protection and the Digital Single Market in Sofia on 16 May 2018, n. 320, p. 11.

59. *Ibidem*.

interest because such measures – also in pandemic times of crisis – are designed to support the public administration procedures of Member States⁶⁰.

They improve the quality and efficiency of public services to guarantee the right to good administration (Article 197 of the TFUE), also enshrined in Article 41 of the “Charter of Fundamental Rights of the European Union”: “Every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions, bodies, offices and agencies of the Union”⁶¹.

The European Commission has long devoted special attention to this matter by issuing directives and action plans to sustain the coordination and collaboration between Member States. Further, it created special instruments, including open data incubators, the official portal for European data, and the Public Sector Information Group. The Commission established the digital single market, announcing “the launch of a new eGovernment Action Plan 2016-2020 to remove existing digital barriers to the Digital Single Market and to prevent further fragmentation arising in the context of the modernisation of public administrations”⁶².

60. On this point, see I. Lindgren, U. Melin, *What is e-government? Introducing a work system framework for understanding e-government*, in *Communication of the Association for Information System*, 2021, p. 2 ss.; S. Hodzic, O. Rausely, *E-government effectiveness and efficiency in EU-28 and Covid-19*, in *Central European Public Administration Review*, 2021, p. 1 ss.; M. Belletti, *Il governo della emergenza sanitaria. Quali effetti sulla Costituzione economica e sul processo federativo europeo*, in *Diritto pubblico europeo*, 2021, p. 20 ss.; A. Campmas, N. Iacob, S. Felice, *How can interoperability stimulate the use of digital public services? An analysis of the National Interoperability Framework and e-Government in the European Union*, 2022; M. Lnenicka, R. Machova, *A theoretical framework to evaluate ICT disparities and digital divides: Challenges and implications for e-government development*, in *Review of Economic Perspectives*, 2022, p. 1 ss.; M. Rispoli Farina, *La Cassa Depositi e Prestiti: intervento ‘paziente’ o ‘dinamico’ a favore delle imprese?*, in *Innovazione e Diritto*, 2022.

61. Article 41, Charter of Fundamental Rights of the European Union, 2010, p. 389, states the following: “(a) the right of every person to be heard, before any individual measure which would affect him or her adversely is taken; (b) the right of every person to have access to his or her file, while respecting the legitimate interests of confidentiality and of professional and business secrecy; (c) the obligation of the administration to give reasons for its decisions. 3. Every person has the right to have the Union make good any damage caused by its institutions or by its servants in the performance of their duties, in accordance with the general principles common to the laws of the Member States. 4. Every person may write to the institutions of the Union in one of the languages of the Treaties and must have an answer in the same language”.

62. European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, EU eGovernment Action Plan 2016-2020. Accelerating the Digital Transformation of Government, 19 April 2016, n. 179, p. 2.

In this context, “E-government public services in Europe have embraced new technologies to varying degrees but more can be done to modernise public administration, achieve cross-border interoperability and facilitate easy interaction with citizens. Online public services are crucial to increasing the cost-efficiency and quality of the services provided to citizens and companies. One example of increased efficiency is the ‘Once Only’ principle, only in 48% of cases do public administrations reuse information about the citizen or companies that is already in their possession without asking again”⁶³.

In fact, “the needs of businesses and citizens in their cross-border activities could be better met by building on the Digital Services Infrastructures of the Connecting Europe Facility and extending and integrating existing European portals, networks, services, and systems (such as Your Europe, Single Points of Contact, Product Contact Points, Contact Points for Construction Products) and linking them to the ‘single digital gateway’. Further, the use of electronic documents should be promoted across the EU to reduce costs and administrative burdens for business and individuals. Businesses are held back by regulatory fragmentation and barriers which makes it harder for them to scale-up and operate across borders within the Internal Market. Many Member States have called for action including helping companies to be formed quickly (e.g., in 24 hours)”⁶⁴.

For these reasons, “the Commission considers that any established company should be able to expand its operations cross-border online and be pan-European within a month building on the interconnection of business registers and the ‘Once-Only’ principle. The Commission will present a new e-Government Action Plan 2016-2020 which will include (i) making the interconnection of business registers a reality by 2017, (ii) launching in 2016 an initiative with the Member States to pilot the ‘Once-Only’ principle; (iii) extending and integrating European and national portals to work towards a ‘Single digital gateway’ to create a user friendly information system for citizens and business

63. Ivi, p. 16. This elaborates how “the extension of this principle, in compliance with data protection legislation, would generate an annual net saving at the EU level of around EUR 5 billion per year by 2017. The Commission will launch a pilot project for the ‘Once-Only’ principle for businesses and citizens and explore the possibility of an EU wide e-safe solution (a secure online repository for documents). Extending ‘Once-Only’ across borders would further contribute to the efficiency of the Digital Single Market. Public procurement represents approximately 19% of EU GDP and EU wide e-procurement is expected to save EUR 50 billion annually. The 2014 public procurement reform package foresees a transition to full e-procurement by October 2018. Increased efforts are needed to meet this target given that in many Member States the transition has started at a slow pace. Contact points between public authorities and citizens/businesses are currently fragmented and incomplete”.

64. Ivi, p. 17.

and (iv) accelerating Member States' transition towards full e-procurement and interoperable e-signatures"⁶⁵.

The e-Government Action Plan 2016-2020 is based on several fundamental issues pertaining to conducting business. It aims to “modernise public administration with ICT, using key digital enablers” because “modern and efficient public administrations need to ensure fast and high-quality services for citizens and a business-friendly environment, as recognised by the recent Annual Growth Surveys. Public administrations need to transform their back offices, to rethink and redesign existing procedures and services, and open their data and services to other administrations, and, as far as possible, to businesses and civil society”⁶⁶.

The Commission emphasizes that “it is essential that EU businesses grasp the opportunities of digital technology to remain competitive at [a] global level, that EU startups are able to scale up quickly, with full use of cloud computing, big data solutions, robotics and high-speed broadband, thereby creating new jobs, increased productivity, resource efficiency and sustainability”. Furthermore, using new e-government instruments “would also bring enormous benefits for people, businesses and public administrations and opens the door to new cross-border opportunities, particularly by using electronic signatures. At the same time, the digital infrastructures on which the digital economy depends need to be robust, resilient, and able to adapt to evolving threats. Otherwise, the trust of people and businesses will be eroded and digital uptake held back”⁶⁷.

The mid-term review on the implementation of the Digital Single Market Strategy assesses the progress toward implementing the Digital Single Market and identifies “where more efforts are needed and where the changing digital landscape calls for new action at the EU level. It is accompanied by the 2017 European Digital Progress Reports outlining the progress made at both EU and Member State level and a staff working document setting out the evidence that has informed this review”⁶⁸.

On this point, the European Commission reiterates that “digital technologies allow public authorities to deliver services more quickly, more precisely, and more efficiently. Many Member States already have major programs of modernization bringing widespread benefits to their citizens. At the EU level, the eGovernment Action Plan 2016-2020 seeks to accelerate

65. *Ibidem*.

66. *Ivi*, p. 5.

67. *Ivi*, p. 3.

68. *Ibidem*.

and broaden the scope of digitization, thereby increasing the efficiency of public administrations and facilitating the free movement of businesses and citizens”⁶⁹.

For example, “companies participating in eProcurement procedures would only need to provide one document”. In this context, “the ‘once-only’ principle at EU level could generate total net savings of around EUR 5 billion/year”, at the same time, “the proposal for a single digital gateway, adopted on 2 May 2017, will help people and businesses to face fewer administrative burdens when moving and/or doing business across borders in the Single Market. It will offer easy access to relevant information and assistance services, it will enable users to complete certain key administrative procedures, online and guarantee non-discriminatory access to national online procedures for users from other countries. It will also set the first step towards implementing the once-only principle in cross border scenarios”⁷⁰.

Digital innovation impacts the entire life cycle of businesses and “will allow companies to fulfil administrative requirements (register, file and update company documents) online and across borders, bringing the benefits of digitization to the process of setting up and maintaining a business”⁷¹.

The 2017 eGovernment Declaration⁷² highlights how “the global landscape is rapidly changing and [...] Europe is facing serious social, environmental, economic and political challenges”⁷³.

Further, “digital progress is transforming our societies and economies to the core, challenging the effectiveness of previously developed policies in a broad range of areas as well as the role and function of the public administration

69. Ivi, p. 17.

70. *Ibidem*; the Commission states that “the public sector can increase the interoperability of their cross-border services by following the recently updated recommendations of the European Interoperability Framework and by sharing their data and services in conformity with the INSPIRE Directive. Use of the ICT standards referenced in a European catalogue would scale up the size of the market for digital products and services”.

71. *Ibidem*. See also the Opinion of the European Economic and Social Committee on ‘Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. A New Industrial Strategy for Europe, 2020, n. 102; it is stated that “the SMEs play a vital role in the process, and ensuring proper financing for them to growth and innovate is vital. The EESC has already mentioned that ‘the Commission should analyse and complement (but not replace) private initiatives for the exchanges of goods practice and experience between innovators’ and that ‘the EU must put in place a political, fiscal and regulatory framework that supports the large-scale deployment of these new sustainable models’ (section 4.2).

72. Tallinn Declaration on eGovernment at the ministerial meeting during Estonian Presidency of the Council of the EU on 6 October 2017.

73. Ivi, p. 2.

overall. It is our duty to anticipate and manage these challenges to meet the needs and expectations of citizens and businesses”⁷⁴.

Consequently, the “development of eGovernment has a central role to play to meet these challenges and make use of the emerging digital opportunities. Amongst others, the digital transformation can strengthen the trust in governments that is necessary for policies to have effect: by increasing the transparency, responsiveness, reliability, and integrity of public governance”⁷⁵.

With reference to the Digital Single Market, “eGovernment is significant for the development of the data economy and the Digital Single Market, especially for ensuring the secure and free movement of data as an enabler for digital innovation in Europe and for reducing the costs of and barriers to seamless functioning of the Single Market”⁷⁶.

3. New tools for digital legal experimentation for regulating smaller enterprises. Innovation facilitators: Digital innovation hubs

The previous sections highlight that for the emergence of a new digital business environment, significant changes must be made to the regulatory framework; further, “while adapting to the digital industrial change is primarily a matter for business, a targeted public policy can play an important part in creating the best conditions for that to happen in all sectors in a competitive environment bolstered by the competition rules. This is particularly important for the vast number of small and medium-sized enterprises that underpin the European economy. Public policy should aim at a thriving digital sector fueling the digitisation of the whole industrial fabric, from construction, health, and agro-food to creative industries”⁷⁷.

The rapid evolution of the current digital environment presents the need for a public regulator to outline new and different ways of defining policies.

Defining new regulation modes capable of keeping pace with the continuous evolution of the market and businesses inevitably requires rethinking the traditional reference model, which faces a series of complex, difficult-to-regulate phenomena.

74. *Ibidem*.

75. *Ibidem*.

76. *Ibidem*.

77. European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Digitising European industry – Reaping the full benefits of a Digital Single Market, 19 April 2016, n. 180, p. 6.

This is “the reason why public authorities, at National and European levels are employing an empirical approach in order to bring the phenomenon back under the Rule of the Law. The preferred approach is developing by means of the so-called ‘innovation facilitators’”⁷⁸.

The term “innovation facilitator” refers to a vast number of instruments; it is “difficult to draw a precise distinction among them, due to the variety of existing models, at EU level and globally. Innovation facilitators can be broadly divided into two main categories: innovation hubs and regulatory sandboxes. These initiatives are not mutually exclusive, with many jurisdictions having put in place more than one type or mixed models”⁷⁹.

In general, “innovation and the use of technology in the financial sector are by no means a new phenomenon. Indeed, it is a sector which is highly susceptible to technological innovation. At the same time, the financial sector is highly regulated in view of its economic significance and its inherent risks. Therefore, the question of a timely and appropriate regulatory response to market innovation as well as the ability of financial sector regulation to accommodate new developments (‘future proofing’) has long been in the focus of policymakers and regulators”⁸⁰.

In this complex environment, “the main challenge for regulators has been to develop new methods of identifying, monitoring, and addressing the changing dynamics in the financial system (such as ever more automated decision making, market power shifts). Jurisdictions across the globe have reacted to FinTech developments in various ways, ranging from bans on certain FinTech activities or products through FinTech specific regulation on certain aspects, to providing some clarification on how the existing regulatory environment would apply to FinTech, without making changes in the existing regulatory framework. In the face of the rapidly changing environment and given the limitations of traditional lawmaking, jurisdictions have also resorted to innovative regulatory approaches to respond to the innovative disruptions. Such approaches include piloting schemes, setting up of innovation offices/hubs, regulatory sandboxes and innovation accelerators, and more recently initiatives focusing on RegTech and SupTech”⁸¹.

78. N. Maccabini, *An empirical approach to the rule of law: The case of regulatory sandboxes*, in *Osservatorio sulle fonti*, 2020, p. 750.

79. R. Parenti, *Regulatory Sandboxes and Innovation Hubs for FinTech*, Study for the Committee on Economic and Monetary Affairs, Policy Department for Economic, Scientific, and Quality of Life Policies, European Parliament, 2020, p. 19.

80. Ivi, p. 16.

81. Ivi, p. 17; see also H.S. Knwetson, A. Rosenbaum, *Toward understanding FinTech and its Industry*, in *Managerial Finance*, 2020, p. 1043; it is stated that “in a surprisingly prescient

The regulator underlines how innovation facilitators offer “opportunities for the authorities to gain a better understanding of innovation in financial services, and for firms to understand better the regulatory and supervisory expectations against the backdrop of rapid technological advancement. In particular, innovation facilitators can help competent authorities to keep pace with developments by gaining near ‘real time’ insights into emerging technologies (such as distributed ledger technologies, big data analytics, artificial intelligence and machine learning) and their application in the financial sector. Competent authorities can apply these insights for the purposes of anticipating regulatory and supervisory issues and responding proactively”⁸².

The relevant authorities can also “react by building up supervisory expertise and resources in relevant areas, confirming and clarifying the application of the regulatory framework to financial innovations and, as appropriate, informing timely updates of regulatory and supervisory practices. In addition, the insights can enable the authorities to adopt a preventative approach, identifying supervisory issues early on, such as emerging risks to consumer protection, and to develop a good understanding of potentially undue regulatory barriers to financial innovation”⁸³.

Innovation facilitators, including smaller ones, can play an important role for regulators and businesses, especially “for new entrants and technology providers, enabling participants to obtain clarifications regarding regulatory and supervisory issues at an early stage”. Further, technology providers “can obtain clarifications of supervisors’ expectations in such contexts. Firms can also use innovation facilitators as platforms to raise policy matters with the competent authorities, for instance regarding areas in which clarifications

manner, FinTech was defined by Bettinger (1972) as “an acronym which stands for financial technology, combining bank expertise with modern management science techniques and the computer”. Nearly fifty years later, the widespread adoption of the personal computer and the existence of the internet and mobile connectivity, the current state of FinTech deserves a fresh treatment. Finance has been characterized by technology throughout its history as noted by Ferguson (2018). He asserts innovations have been the cornerstone of finance... Yet it appears that FinTech has unleashed something beyond the normal path of financial technology. How rapid is its advance now? A search ABI/INFORM shows the usage of the term FinTech has grown twenty-five-fold over the past decade to over 1,000,000 works containing the term FinTech, spawned by a new industry of FinTech firms”. However, regarding FinTech, “the Financial Stability Board (FSB), an international body of representatives from over 20 countries [that] provides oversight of the international financial system, published a paper about FinTech oversight in 2017 (Willinks et al., 2017). The FSB connects FinTech innovations to the world economy with a regulatory framework to mitigate FinTech risks” (p. 1046).

82. ESMA, EBA, EIPOA, *Joint report on FinTech: Regulatory sandboxes and innovation hubs*, 2018, p. 33.

83. *Ibidem*.

may be required in the application of the regulatory framework to financial innovations”⁸⁴.

Regulators face numerous challenges, including “keeping pace with industry”. That is, “some authorities noted the difficulties in finding and retaining staff with the appropriate knowledge and experience of FinTech, noting the pace of change in the financial sector and variety of innovations proposed”⁸⁵.

Another challenge is “domestic coordination”: “some authorities noted that enquiries raised through the innovation hubs, and propositions tested in regulatory sandboxes, often involve cross-cutting issues going beyond their direct sphere of responsibility (e.g. queries giving rise to data protection and regulatory perimeter issues). They also noted challenges in providing complete and prompt responses in this context. Many, in the absence of multi-disciplinary innovation facilitators, referred firms to other relevant domestic authorities, so firms needed to initiate separate discussions”. Lastly, “cross-border cooperation” is a challenge; “the current framework guiding interactions between authorities on issues giving rise to cross border considerations might not be fully adapted to financial innovations (e.g. where a firm may wish to apply an innovative product or service in more than one jurisdiction and seeks guidance from the competent authorities about the appropriate regulatory treatment in each jurisdiction) and could give rise to delays in providing coordinated and holistic responses”⁸⁶.

Innovation facilitators are “a structured environment for engagement and knowledge exchange between supervisors and innovative companies. For new entrants, facilitators ‘enable access to dedicated supervisory resources with specialist expertise’, which supports the company in navigating through the licensing procedures and the wider regulatory framework”⁸⁷.

Facilitator schemes also “help them develop a much better understanding of supervisory expectations. This allows companies to develop their products, services or business model in a regulation-compliant way from the design stage, thus avoiding potential legal risks later on”⁸⁸.

Innovation facilitators may be capable of “‘reducing the time-to-market cycle’ for new products and, reportedly, an admission to a sandbox can also

84. Ivi, p. 34.

85. *Ibidem*.

86. *Ibidem*.

87. R. Parenti, *Regulatory Sandboxes and Innovation Hubs for FinTech, Study for the Committee on Economic and Monetary Affairs, Policy Department for Economic, Scientific, and Quality of Life Policies, European Parliament*, p. 22.

88. *Ibidem*.

improve financing opportunities for new companies. In some cases, the facilitator schemes allow the companies ‘some time before they have to meet the requirements of the prudential framework in full’⁸⁹.

At the same time, from a public regulators’ perspective, innovation facilitators ensure a continuous dialogue and sharing of opinions between institutions and companies of all sizes, allowing public authorities to acquire “the knowledge and necessary elements to assess whether the regulatory perimeter needs to be adjusted”⁹⁰.

However, there are risk elements associated with innovation facilitators and “perhaps the most common concern about the use of innovation facilitators is the potential for regulatory arbitrage”⁹¹.

The concern “is that some regulators are opting for a ‘race-to-the bottom’ in a bid to attract start-ups and investors. A ‘race-to-the bottom’ style competition between regulators, in the longer run, could lead to compromises on consumer protection and financial stability. This risk is not specific to innovation facilitators: a de-regulatory potential may emerge from various measures adopted by jurisdictions to attract FinTech”⁹².

Further, “there are also broader concerns about potential negative impacts on consumer protection and financial stability. In view of the trade-offs that regulators are facing between their different regulatory objectives, critics point to the risk that they may prioritize innovation over putting adequate safeguards in place to protect the public and consumer interest”⁹³.

Regarding the Digital Single Market, the innovation facilitators “bear a risk of market fragmentation”⁹⁴.

Innovation hubs⁹⁵ among innovation facilitators are particularly relevant to our study.

89. Ivi, p. 23.

90. *Ibidem*.

91. Ivi, p. 24.

92. *Ibidem*.

93. Ivi, p. 25.

94. *Ibidem*.

95. A. Georgescu, S. Avasilcai, M.K. Peter, *Digital innovation hubs. The present future of collaborative research, business and marketing development opportunities*, in A. Roch, J. Reis, M.K. Peter, R. Cayolla, S. Loureiro, S. Bogdanović (eds.), *Marketing and Smart Technologies. Smart Innovation, Systems, and Technologies*, Springer, 2021; G. Dalmarco, V. Teles, O. Uguen, A. Barros, *Digital innovation hubs: One business model fits all?*, in L. Camarinha-Matos, X. Boucher, A. Afsarmanesh (eds.), *Smart and Sustainable Collaborative Networks 4.0*, Springer, 2021, p. 428 ss.; J. Hervas-Oliver, G. Gonzalez-Alcaide, R. Rojas-Alvarado, S. Monto Mompo, *Emerging regional innovation policies for industry 4.0: Analysing the digital innovation hub program in European regions*, in *Competitiveness Review*, 2021, p. 106; M.

Innovation hubs originate in the financial market⁹⁶, where they represent “a platform to exchange knowledge and informal guidance”⁹⁷ and a “fresh perspective in the way organizations should (and could) perceive digital innovation, and how they can adapt and apply its concepts and opportunities in a business context”⁹⁸.

Innovation hubs “usually provide a specific scheme via which firms can engage with the supervisor to raise questions and seek clarifications or non-binding guidance about FinTech related issues in the context of compliance with the regulatory framework, licensing or registration requirements, and regulatory and supervisory expectations”⁹⁹.

The innovation gap is significant for companies of all sizes¹⁰⁰ to such an extent that “industrial stakeholders point out the urgent need for ‘facilities to experiment with and test digital innovations’ before investing in digitization. Regions and cities with a higher digital readiness had invested in digital competence centers (e.g. research and technology organizations (RTOs) and university labs) offering such support to industry. As regions with strong clusters in digital industries are characterized with very high innovation levels, there is also scope to better use clusters with technology infrastructure and innovation intermediaries”¹⁰¹.

In a 2018 joint report, the European Banking Authority (EBA), European Securities and Markets Authority (ESMA), and European Insurance and

Lanz, J. Latokartano, R. Pieters, *Digital innovation hubs for enhancing the technology transfer and digital transformation of the European manufacturing industry*, in S. Ratchev (ed.), *Smart Technologies for Precision Assembly*, Springer, 2021, p. 210 ss.

96. See R. Di Raimo, *I mercati finanziari digitalizzati: una struttura da disciplinare che crea nuove opportunità*, in *FCHub. Financial Community Hub*, 2018.

97. R. Parenti, *Regulatory Sandboxes and Innovation Hubs for FinTech*, *Study for the Committee on Economic and Monetary Affairs, Policy Department for Economic, Scientific, and Quality of Life Policies*, European Parliament, p. 20.

98. A. Georgescu, S. Avasilcai, M.K Peter, *Digital innovation hubs. The present future of collaborative research, business and marketing development opportunities*, in A. Roch, J. Reis, M.k. Peter, R. Cayolla, S. Loureiro, S. Bogdanović (eds.), *Marketing and Smart Technologies. Smart Innovation, Systems, and Technologies*, p. 365.

99. R. Parenti, *Regulatory Sandboxes and Innovation Hubs for FinTech*, *Study for the Committee on Economic and Monetary Affairs, Policy Department for Economic, Scientific, and Quality of Life Policies*, European Parliament, p. 20.

100. European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, *Digitising European industry – Reaping the full benefits of a Digital Single Market*, 19 April 2016, n. 180, p. 8; it is stated that “around 60% of large industries and more than 90% of SME feel lagging behind in digital innovation. Similarly, there are strong digitisation discrepancies between industrial sectors”.

101. *Ibidem*.

Occupational Pensions Authority (EIOPA) defined an innovation hub as “a scheme whereby regulated or unregulated entities can engage with competent authorities on FinTech-related issues and seek non-binding guidance on the conformity of innovative financial products, services, business models or delivery mechanisms with licensing, registration and/or regulatory requirements”¹⁰².

The main objective of innovation hubs appears to be to “enhance firms’ understanding of the regulatory and supervisory expectations regarding innovative business models, products and services. This is done by providing firms with a contact point for asking questions of, and initiating dialogue with, competent authorities regarding the application of regulatory and supervisory requirements to innovative business models, financial products, services and delivery mechanisms”¹⁰³.

European regulators, in turn, describe the phases of innovation hubs. The first phase is related to a “submission of enquiries: interface between competent authorities and firms”. This is configured as “dedicated contact channels for questions regarding the conformity of innovative financial products, services, business models or delivery mechanisms with regulatory and/or licensing requirements”¹⁰⁴.

The second phase relates to “assigning queries to the relevant points of contact in the competent authorities”. Specifically, “once a firm has made contact with the competent authority using the interface, typically the authority conducts a screening process to determine how best to deal with the queries raised. The authority considers factors such as the nature of the query, its urgency and its complexity, including the need, if any, to refer the query to other authorities or to engage with other authorities, such as data protection authorities, in preparing the response. This may comprise a ‘pre-screening’ by a dedicated team prior to submission to relevant experts, or direct submission either to the relevant working groups or multi-disciplinary teams in the authority or to other competent authorities, in accordance with the organisation of financial supervision in the Member State concerned”¹⁰⁵.

The third phase is “providing responses to the firms”; “typically, the responses provided via the innovation hub are to be understood as ‘preliminary guidance’ based on the facts established in the course of the communications between the competent authorities and firms”¹⁰⁶. The fourth phase involves

102. ESMA, EBA, EIOPA. *Joint report on FinTech: Regulatory sandboxes and innovation hubs*, 2018, p. 7.

103. Ivi, p. 8.

104. Ivi, p. 9.

105. Ivi, p. 10.

106. Ivi, p. 11.

“record keeping and transparency”, and the fifth and ultimate phase corresponds to “follow-up actions”, where “some competent authorities complement their innovation hubs with specific ‘follow-up’ schemes in order to facilitate and support firms. In particular, in cases where a firm seeks to advance a concept for a business model, and its interactions with the innovation hub have identified that the model requires the carrying out of a regulated activity for which authorization is required, some competent authorities may provide support with the authorisation process (e.g. dedicated points of contact, guidance on the completion of the application form). In addition, some competent authorities conduct specific reviews of the enquiries raised and the responses provided via the innovation hubs in order to assess the need for clarifications of, or changes to, regulatory and supervisory requirements to ensure that they take account of the opportunities and risks presented by financial innovations and the desirability of ensuring technological neutrality”¹⁰⁷.

For SMEs, innovation hubs are a fundamental tool in becoming “more competitive with regard to their business/production processes, products or services by using digital technologies”¹⁰⁸. Furthermore, “in 40% of DHIs, a focus on SMEs is expressed in their mission and activities, and in 9%, SMEs are described as the only clients of the DIHs. In addition, 19% outline an interest in SMEs mainly as a result of a regional, national or European project”¹⁰⁹.

The European Commission and the European Investment Bank also analyzed the role of innovation hubs in the report *Financing the Digitalisation of Small and Medium-sized Enterprises: The Enabling Role of Digital Innovation Hubs*. The report states that “the services available through digital innovation hubs may be categorised under three pillars: 1) innovation activities: concerned with identifying opportunities for digitalisation and developing and validating innovative solutions based on cutting-edge technologies, 2) business development: concerned with helping companies apply their solutions, assess

107. *Ibidem*.

108. A. Crupi, N. Del Santo, A. Di Minin, G. Gregori, D. Lepore, L. Marinelli, F. Spigarelli, *The digital transformation of SMEs – A new knowledge broker called the digital innovation hub*, in *Journal of Knowledge Management*, 2020, p. 1264 ss. See also: S. Sassanelli, S. Terzi, H. Panetto, G. Doumeingts, *Digital innovation hubs supporting SMEs digital transformation*, in *IEEE International Conference on Engineering, Technology and Innovation*, 2021; F. Maurer, *Business intelligence and innovation: A digital innovation hub as intermediate for service interaction and system innovation for small and medium-sized enterprises*, in L. Camarinha-Matos, X. Boucher, H. Afsarmanesh (eds.), *Smart and Sustainable Collaborative Networks 4.0*, Springer, 2021.

109. A. Crupi, N. Del Santo, A. Di Minin, G. Gregori, D. Lepore, L. Marinelli, F. Spigarelli, *The digital transformation of SMEs – A new knowledge broker called the digital innovation hub*, in *Journal of Knowledge Management*, p. 1271.

the business implications/impact and manage changes to business models and 3) skills development: concerned with building innovation capacity through upskilling”¹¹⁰.

It follows from this analysis that “digital innovation hubs play a crucial role but there is potential to strengthen their offering”. It is necessary to “strengthen the contribution of digital innovation hubs to the digitalisation of industries across Europe and, as such, help them recover from the impact of the coronavirus pandemic”¹¹¹.

At the same time, “public funding is dominant for digital innovation hubs, but new financing models are emerging”. In fact, “most digital innovation hubs have a mixed funding model, but there is a high dependency on public funding from European, national or regional programmes”. However, “there is a growing (but limited) number of digital innovation hubs focused on developing more commercial services and activities. This expanded offering, which means going into revenue-generating activities, is an important step to develop sustainable and more commercially-oriented business models, paving the way to a more diversified and sustainable funding base”¹¹².

The need to sustain the digital transformation of SMEs and the role of innovation hubs is also emphasized in the recent EU Regulation 2021/694, “Establishing the Digital Europe Programme”, of April 29, 2021. The regulation underlines that “a central role in the implementation of the Programme should be attributed to European Digital Innovation Hubs, which should stimulate the broad adoption of advanced digital technologies by industry, in particular by SMEs”¹¹³.

The regulation cited above defines a European Digital Innovation Hub (EDIH) as “a legal entity selected in accordance with Article 16 in order to fulfil the tasks under the Programme, in particular by directly providing, or ensuring access to, technological expertise and experimentation facilities, such as equipment and software tools to enable the digital transformation of industry, as well as by facilitating access to finance and it is open to businesses of all forms and sizes, in particular to SMEs, midcaps and scale-up companies, and to public administrations across the Union”¹¹⁴.

110. European Investment Bank, European Commission, Financing the digitalisation of small and medium-sized enterprises: The enabling role of digital innovation hubs, 2020, p. 12.

111. *Ivi*, p. 78.

112. *Ibidem*.

113. Whereas n. 16, Regulation EU 2021/694, Establishing the Digital Europe Programme, 29 April 2021.

114. Article 2,5 Regulation EU 2021/694.

Article 16 introduces the concept of a “network of European Digital Innovation Hubs”, where each Member State must provide “candidate entities in accordance with its national procedures, administrative and institutional structures through an open and competitive process”¹¹⁵.

EDIHs are assigned “to the benefit of the Union industry, in particular SMEs and mid-caps, as well as the public sector”¹¹⁶.

EDIHs carry out tasks relative to “(a) raising awareness and providing or ensuring access to digital transformation expertise, knowhow and services, including testing and experimentation facilities”; “(b) assisting businesses, especially SMEs and start-ups, organisations and public administrations to become more competitive and to improve their business models through use of new technologies covered by the Programme”; “(c) facilitating the transfer of expertise and knowhow between regions, in particular by matching SMEs, start-ups and mid-caps established in one region with European digital innovation hubs established in other regions that are best suited to providing relevant services; encouraging exchanges of skills and knowledge, joint initiatives and good practices”; “(d) providing or ensuring access to thematic services, in particular services related to AI, HPC and cybersecurity and trust to the public administrations, public sector organisations, SMEs or mid-caps”; and “(e) providing financial support to third parties under Specific Objective 4”¹¹⁷.

Therefore, it is clear that digital regulatory interventions and instruments are taking on an increasingly significant role within the market to facilitate a concrete and effective digitalization process in the European industrial sector. In the absence of adequate support, it is evident that SMEs could not fully take advantage of the countless opportunities in the digital market.

115. Article 16 Regulation EU 2021/694 presents the following criteria: “(a) the appropriate competences related to the activities of the European Digital Innovation Hubs referred to in paragraph 6 of this Article and competences in one or several areas identified in Article 3(2)”; “(b) the appropriate management capacity, staff and infrastructure necessary to carry out the activities referred to in paragraph 6 of this Article”; “(c) the operational and legal means to apply the administrative, contractual and financial management rules laid down at Union level”; and “(d) the appropriate financial viability corresponding to the level of Union funds it will be called upon to manage and demonstrated, where appropriate, through guarantees issued preferably by a public authority”.

116. Article 16,6, Regulation (EU) 2021/694 of 29 April 2021, Establishing the Digital Europe Programme.

117. Article 16,6, Regulation (EU) 2021/694 of 29 April 2021, Establishing the Digital Europe Programme.

4. Regulatory Sandboxes for SMEs

Regulatory sandboxes fall into the vast category of instruments commonly known as innovation facilitators, which have been examined in the previous section.

They originated as a part of the digital experimentation within the financial market¹¹⁸ and continue to this day.

As we know, public regulation of digital phenomena in the financial market, as in other markets, “requires regulators to balance support for innovation with their core regulatory mandates of financial stability and consumer protection. Four main approaches have so far emerged to meet this challenge”¹¹⁹.

The approaches can be framed as “doing nothing (which could be a restrictive or a permissive approach, depending on context), cautious permissiveness

118. J. Truby, R.D. Brown, I.A. Ibrahim, O. Caudevilla Parellada, *A sandbox approach to regulating high-risk artificial intelligence applications*, in *European Journal of Risk Regulation*, Cambridge, 2022, p. 277; it is suggested that “the ‘sandbox’ concept is particularly utilised in the areas of financial innovation and FinTech, where a regulator enables experimental innovation within a framework of controlled risks and supervision. This allows a ‘form of ‘beta testing’ for financial technology start-ups, where firms may test their financial services technology and other financial products under supervision of the financial services authorities”. Further, regulatory sandboxes are still a widely used instrument in the financial market today. For example, on February 14, 2023, the European Commission launched the European Regulatory Sandbox for Blockchain, which will provide “legal certainty for decentralised technology solutions including blockchain by identifying obstacles to their deployment from a legal and regulatory perspective and providing legal advice, regulatory experience and guidance in a safe and confidential environment. It should also allow regulators and supervisors to enhance their knowledge of cutting-edge blockchain technologies and share best practices through dialogues”. This Sandbox “is supported by the Digital Europe Programme, the EU funding programme focused on bringing digital technology to businesses, citizens and public administrations. It will also help Europe reach its ambition for digital leadership in the Digital Decade, as reducing the legal uncertainty around blockchain will enable its uptake across sectors”: digitalstrategy.ec.europa.eu/en/news/launch-european-blockchain-regulatory-sandbox. See G. Lo Sapio, *Il regolatore alle prese con le tecnologie emergenti. La regulatory sandbox tra i principi dell’attività amministrativa e rischio di illusione normativa*, in *Federalismi.it*, 2022, p. 88 ss.

119. D.A. Zetsche, R.P. Buckley, J.N. Barberis, D. Arner, *Regulating a revolution: From regulatory sandboxes to smart regulation*, in *Fordham Journal of Corporate & Financial Law*, 2018, p. 43. See also I. Chiu, *A rational regulatory strategy for governing financial innovation*, in *European Journal of Risk Regulation*, 2017, p. 757, which states, “Vermeulen et al. support a pro-active role for regulators in relation to financial innovation. Regulators need to assess whether socially costly regulatory barriers should be adjusted and whether innovative activities need to be governed in order not to compromise public interest objectives. However, the pro-active approach towards regulation and innovation comes with a few hazards. This approach risks having a preponderant pro-innovation bias and can fall short of providing governance for financial innovation”.

through flexibility and forbearance (under which existing rules are relaxed in specific contexts), restricted experimentation (for example sandboxes or piloting), and regulatory development (in which new regulations are developed to cover new activities and entrants)¹²⁰.

The first approach is “doing nothing: either by intent or otherwise. Doing nothing can involve simply not regulating FinTech and the result can be either permissive or laissez-faire depending upon whether current banking regulation applies to the sector”¹²¹.

With regard to the second approach, “regulators can choose to allow certain amounts of flexibility on a case-by-case basis, in what could be classified as a cautiously permissive approach based on forbearance”¹²².

The third approach highlights that “regulators can provide a structured context for experimentation by instituting a regulatory sandbox or [...] structured piloting exercises [...]. At the most basic level, the sandbox creates an environment for businesses to test products with less risk of being ‘punished’ by the regulator. In return, regulators require applicants to incorporate appropriate safeguards [...]. Eligibility to enter a sandbox is standardized and publicized, thus requiring market participants to articulate their added value in a pre-defined format. This is cost effective for participants and resource-effective for regulators, allowing easier comparison among potential entrants to the sandbox”¹²³.

Finally, the fourth approach is linked to the idea that “existing regulations are reformed, or new regulations are developed in order to provide a more appropriate and balanced framework for new entrants and new activities”¹²⁴.

Historically, “the theoretical basis of sandbox concepts originates from the information technology (IT) sector. Primarily in the context of software development, sandboxes provide an isolated testing environment for new codes before merging into the ‘live’ system. This approach facilitates the identification of and protection against malfunctions or other changes that could inflict damage to the overall system resulting in potentially high costs”¹²⁵.

120. D.A. Zetsche, R.P. Buckley, J.N. Barberis, D. Arner, *Regulating a revolution: From regulatory sandboxes to smart regulation*, in *Fordham Journal of Corporate & Financial Law*, p. 35.

121. Ivi, p. 43.

122. Ivi, p. 44.

123. Ivi, p. 45.

124. Ivi, p. 46.

125. J. Gerlach, D. Rugilo, *The predicament of fintechs in the environment of traditional banking sector regulation. An analysis of regulatory sandboxes as a possible solution*, in *Credit and Capital Markets*, 2019, p. 335.

The UK's Financial Conduct Authority (FCA) was the first to initiate a financial regulatory environment "in November 2015 as a core component of its 'Project Innovate' initiative [...]. Afterwards, the application of sandbox concepts spread rapidly across various countries [...]. However, most introduced sandboxes are not constructed uniformly nor are they at the same stage of implementation [...], reflecting the differing size and maturity of the particular financial sectors and the flexibility of the regulatory frameworks already in place [...]. However, albeit the diversity of existing models, the majority of sandboxes share some key characteristics and design components [...]. If successfully implemented, regulatory sandboxes have the potential to lower regulatory barriers and help to speed up the market introduction of a wide range of new services. Furthermore, the gathered information and valuable insights during the test period might assist regulators to gain better understanding of risks and how to adapt current and future regulation to FinTechs without stifling innovation"¹²⁶.

In 2017, the FCA confirmed that "the FCA's philosophy has been one of 'technology neutrality' i.e. not to regulate specific technology types, only the activities they facilitate and the firms carrying out these activities. This approach is designed to accommodate innovation but avoid arbitrage and unfair competition"¹²⁷, but now it is necessary to "explore emerging business models, and how their potential risks and opportunities operate in the context of our regulatory framework"¹²⁸.

The UK FCA defines a sandbox as "a 'safe space' in which businesses can test innovative products, services, business models and delivery mechanisms without immediately incurring all the normal regulatory consequences of engaging in the activity in question"¹²⁹.

More specifically, regulatory sandboxes can be defined as a "controlled environment or safe space in which FinTech start-ups or other entities at the

126. *Ibidem*, p. 335.

127. R. Mangano, *Blockchain securities, insolvency law and the sandbox approach*, in *European Business Organization Law Review*, 2018, p. 727, states that the establishment of sandboxes by the FCA is interesting for two reasons. First, the FCA "has replaced the more traditional 'commanding and controlling' approach with a form of problem-solving behaviour which aims at exploring the new setting and investigating the essential nature of the challenge that the new setting is posing for regulators" and, second, because "it is laying the basis for a form of cooperation between the FCA and the stakeholders of the blockchain financial industry which is proving to be beneficial for both the parties".

128. *Ibidem*.

129. J. Truby, R.D. Brown, I.A. Ibrahim, O. Caudevilla Parellada, *A sandbox approach to regulating high-risk artificial intelligence applications*, in *European Journal of Risk Regulation*, p. 277.

initial stages of developing innovative projects can launch their businesses under the ‘exemption’ regime in the case of activities that would fall under the umbrella of existing regulations or the ‘not subject’ regime in the case of activities that are not expressly regulated on account of their innovative nature, such as initial coin offerings, crypto currency transactions, asset tokenisation, etc.”¹³⁰.

Thus, “a sandbox both enables entrepreneurial development and informs regulatory policy” and, as such, offers “several advantages to technology developers, including the ability to verify and demonstrate an innovative technology by testing it in a live environment with real consumers”¹³¹.

In fact, “direct communication between developers and regulators creates a more cohesive and supportive industry. Successive trial-and-error testing within a controlled environment mitigates the risks and unintended consequences such as unseen security flaws when a new technology gains market adoption. It is in this context, for instance, that the financial sector implemented regulatory sandboxes to avoid such flaws given the importance of this sector to any global economy. Hence, similar reasoning should follow when it comes to AI activities. A supplementary goal of the sandbox is for regulators themselves to learn and understand the product or service better”¹³².

This allows the regulator “to develop policy and regulations to accommodate, supervise and control sectoral innovation within and outside of the sandbox. Regulations tested within the sandbox can determine the most appropriate framework for real-world regulations outside of the sandbox. Updating regulations and ending regulatory uncertainty would make the jurisdiction a more attractive destination for technology developers and investors”¹³³.

130. *Ibidem*. See M. Semeraro, *Moneta legale, moneta virtuale e rilevanza dei conflitti*, in *Rivista di Diritto bancario*, 2019, p. 237 ss.; F. Sartori, U. Malvagna, *Cryptocurrencies as “fungible digital assets” within the Italian legal system: regulatory and private law issue*, in *The Italian Law Journal*, 2022, p. 481 ss.; G. Rotondo, E. Coraggio, *Monete virtuali: tassonomia e inquadramento giuridico*, in *Innovazione Diritto*, 2022.

131. J. Truby, R.D. Brown, I.A. Ibrahim, O. Caudevilla Parellada, *A sandbox approach to regulating high-risk artificial intelligence applications*, in *European Journal of Risk Regulation*, p. 277.

132. *Ibidem*.

133. *Ibidem*, discuss Quan’s perspective. They warn “regulatory uncertainty is the result of outdated regulations unable to catch up with innovation. Regulatory fear, on the other hand, is caused by risk-averse regulators unwilling or unable to green-light novel products that may be perfectly compliant with regulations”. The authors also specify, “as jurisdictions rush to develop their sandboxes, Quan cautions on the importance of properly implementing a sandbox, as ‘too often sandboxes are misunderstood, misused, or mismanaged’. Regulatory agencies should use sandboxes to keep up to date with fast-paced innovation and promote market competition without sacrificing consumer protection. Real innovation-minded regulatory agencies see sandboxes as means, not ends” (p. 278).

According to the analysis put forward by the EBA, ESMA, and EIOPA, regulatory sandboxes “provide a scheme to enable firms to test, pursuant to a specific testing plan agreed and monitored by a dedicated function of the competent authority, innovative financial products, financial services or business models. Sandboxes may also imply the use of legally provided discretions by the relevant supervisor (with use depending on the relevant applicable EU and national law) but sandboxes do not entail the disapplication of regulatory requirements that must be applied as a result of EU law”¹³⁴.

The aim “is to provide a monitored space in which competent authorities and firms can better understand the opportunities and risks presented by innovations and their regulatory treatment through a testing phase, and to assess the viability of innovative propositions, in particular in terms of their application of and their compliance with regulatory and supervisory requirements”¹³⁵.

From the analysis emerge some “objectives underpinning the establishment of the regulatory sandboxes”, as follows: “to enhance firms’ understanding of regulatory expectations, in particular, the applicability of the existing regulatory framework to innovative business models, products and services”; “to increase the knowledge of the authorities about financial innovations, the risks posed and the opportunities provided (e.g. regarding consumer protection), and to inform their approach to the regulation and supervision of financial innovations through direct testing”; and “to foster innovation”¹³⁶.

The European Supervisory Authorities characterize regulatory sandboxes according to the following stages of development: “an application phase, a preparation phase, a testing phase and an exit or evaluation phase with a decision on the approach to the exit from the regulatory sandbox (with either the continuation or the discontinuation of the activities)”¹³⁷.

During the application phase, in the case of three Member States, Lithuania, Netherlands, and Poland, “firms may submit an application to participate in the regulatory sandbox at any time”. In the case of two countries, “the competent authorities have run ‘cohort’ processes under which applicants are able to apply for testing during designated periods. The application window is typically open for a period of up to two months and applicants are able to apply for testing in the regulatory sandbox by completing and submitting a standardized application form [...]. Applications are judged by the competent authorities

134. ESMA, EBA, EIOPA, *Joint report on FinTech: Regulatory sandboxes and innovation hubs*, 2018, p. 5.

135. Ivi, p. 16.

136. Ivi, p. 19.

137. Ivi, p. 22.

against set, transparent, publicly available criteria. All applications are judged against these criteria and only proposals that meet the criteria will be accepted for testing”¹³⁸.

In the preparation phase, the competent authorities work together with the companies admitted to the trial to define the functional aspects of the sandbox such as “operational requirements need to be put in place to support the test”, “the parameters for the test”, and “the plan for the engagement between the firm and the competent authority during the testing phase”, and “appropriate disclosures to or communications with the relevant costumers of the firm, the competent authority and other relevant authorities (such as data protection or customer protection authorities) during the testing phase”¹³⁹.

The testing phase “allows sufficient opportunity for the proposition to be fully tested and for the opportunities and risks to be explored”¹⁴⁰.

This phase consists of varied durations in different jurisdictions. During this period, “the firm is expected [...] to communicate with the competent authority through a direct on-site presence, meetings, regulator calls or pre-agreed written reports. Competent authorities experience this close interaction throughout the testing phase as more intense supervision than the usual supervisory engagement, [...] pursuant to the engagement plan agreed at the preparation stage”¹⁴¹.

The testing phase also represents a key moment for the regulatory sandbox as for the authorities, “the value of the testing phase can be found in the opportunity to understand the application of the regulatory framework with regard to the innovative proposition and in the opportunity to build in appropriate safeguards for innovative propositions, for example, with regard to consumer protection considerations. This may involve a reassessment of the regulatory perimeter (in the context of determining how the proposition fits within the regulatory framework) or a recalibration of the regulatory requirements within the existing framework to ensure proportionality and technical neutrality”¹⁴².

The final phase of evaluation occurs both on the business side and on the side of the authorities, and the “‘success’ can be measured in many ways (as agreed during the pre-testing phase) and may include determining quickly that it is not possible for a proposition to be viably applied in the light of the existing regulatory and supervisory obligations to mitigate the risks identified”¹⁴³.

138. *Ibidem*.

139. Ivi, p. 25.

140. Ivi, p. 27.

141. *Ibidem*.

142. Ivi, p. 28.

143. Ivi, p. 29.

Therefore, regulatory sandboxes broadly “provide a promising solution to the occurring trade-off between sound regulation and innovative support, without threatening financial stability or degrading consumer protection”¹⁴⁴. The regulator can use these in as much as “an official sandbox policy with legislative endorsement reduces the risk of litigation for breach of a regulator’s supervisory duties”¹⁴⁵.

The regulatory sandbox “assists regulators in achieving an efficient level of dispensation, enabling them to better weigh the pros and cons for society rather than for themselves”¹⁴⁶.

Further, the regulatory sandbox may begin a “friendly view of innovation in general”¹⁴⁷ and result in “friendly treatment ‘outside the box’”, such that “financial entrepreneurs and established institutions may decide to locate their innovations and new jobs in these jurisdictions”¹⁴⁸.

In other words, regulatory sandboxes “go a step further and provide a special scheme, in which companies can test innovative financial products, services, or business models with actual customers in a controlled environment (a ‘sandbox’) pursuant to a specific testing plan agreed with the supervisor and subject to the application of distinct safeguards”¹⁴⁹.

A regulatory sandbox “usually implies some lenience or supervisory discretion about the way in which the regulatory framework applies to innovative products or services”¹⁵⁰.

Furthermore, at an international level, it has been observed that “digital technologies carry a promise to fast track sustainable development by supporting innovative, forwarding-looking policies and digital government solutions. There are, however, numerous risks and complexities of frontier technologies that come along with those opportunities, as well as policy and regulatory challenges such as those related to inclusion, competition, privacy and security”. In this context, “innovation hubs, incubators, accelerators, or

144. M. Gerlach., D. Rugilo, *The predicament of fintechs in the environment of traditional banking sector regulation. An analysis of regulatory sandboxes as a possible solution*, in *Credit and Capital Market*, p. 324.

145. D.A. Zetzsche, R.P. Buckley, J.N. Barberis, D. Arner, *Regulating a revolution: From regulatory sandboxes to smart regulation*, in *Fordham Journal of Corporate & Financial Law*, p. 81.

146. *Ibidem*.

147. *Ibidem*.

148. *Ibidem*.

149. R. Parenti, *Regulatory Sandboxes and Innovation Hubs for FinTech*, *Study for the Committee on Economic and Monetary Affairs, Policy Department for Economic, Scientific, and Quality of Life Policies, European Parliament*, p. 20.

150. *Ibidem*.

testbeds have since emerged as springboards for new technologies and are now common in many developed and developing countries. In some scenarios, however, the perceived risks and costs of failure in public sector innovation mean that policymakers and regulators may still prefer to stick to the status quo¹⁵¹.

Recently, “relatively new approaches of sandboxes and experiments have emerged among some countries and have proven to be effective in creating a more conducive and contained space where governments, in partnerships with the private sector and other relevant stakeholders, are able to test technologies in a controlled space with a small sample group before launching them at scale, allowing one to dramatically reduce costs and limit the chances of failure and negative impacts”¹⁵².

Sandboxes, which, as mentioned above, originated within the financial market and specifically within FinTech, have come up in some countries “through public-private partnerships (PPP) or multistakeholder partnerships (MSP)”. For example, the UK FCA “has established a regulatory sandbox for enabling more efficient small medium enterprises (SME) lending and supporting the development of digital ID in the financial sector, specifically aiming at consumers and SMEs”¹⁵³.

In this sense, regulatory sandboxes can “help small firms such as startups and ventures to lead innovation and attract investment. In addition, one of the primary goals of regulatory sandboxes is to attract the attention of investment sources such as banks, private equity, and venture capital funds”¹⁵⁴.

151. UN Department of Economic and Social Affairs, *Sandboxing and experimenting digital technologies for sustainable development*, December 2021, p. 1, states that, among the “Key Messages”, “the promise of sandboxes and experiments allows evidence-based decision-making and adaptive deployment of digital technologies in the pursuit of e-government aims. It allows institutions and regulators to experiment and trial with digital technologies and innovations at the edge or even outside of the existing policy space and regulatory framework”.

152. *Ibidem*.

153. *Ibidem*, also highlights that “In Singapore, the Energy Market Authority (EMA) implemented a regulatory sandbox for the energy sector, with the primary focus on innovation in the sectors of electricity and gas, aiming to find innovative solutions for future renewable energy sources”. The “Key Messages” also specify that sandboxes can be applied to other sectors (not just finance) “including health, education, transport, energy, connectivity and the digital economy, in fast-tracking smart, risk-aware implementation of digital technologies and in accelerating the implementation of the sustainable development goal”.

154. J. Goo, J. Heo, *The impact of the regulatory sandbox on the fintech industry, with a discussion on the relation between regulatory sandboxes and open innovation*, in *Journal of Open Innovation*, 2020, p. 2. The authors say that “regulatory sandboxes have an effect that promotes the investment of venture capital into the fintech industry. In the high-tech industry, the activation of venture investment is an important factor in the early-stage industrial maturity. This significant

The link and significant potential for synergy between sandboxes and SMEs are evident; further, this is mentioned in the European Council’s Conclusions on Regulatory Sandboxes and Experimentation Clauses as Tools for an Innovation-Friendly, Future-Proof and Resilient Regulatory Framework that Masters Disruptive Challenges in the Digital Age, November 16, 2020. It is stated that “both regulatory sandboxes and experimentation clauses have practical uses beyond FinTech, and in technological growth generally”¹⁵⁵.

In these conclusions, “the Council encourages the EC to continue considering the use of experimentation clauses on a case-by-case basis when drafting and reviewing legislation, as well as to evaluate the use of experimentation clauses in ex post evaluations and fitness checks on the basis of an exchange of information with Member States. Conclusion Number 8 defines regulatory sandboxes as ‘concrete frameworks which, by providing a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place’”¹⁵⁶.

These conclusions are consistent with the other two documents, the “Coordinated Plan on Artificial Intelligence” and the “Resolution of 12 February 2019 on a comprehensive European industrial policy on AI and robotics 2018/2088” “since it insists on the opportunities offered by regulatory sandboxes”. Further, “the Council affirms that regulatory sandboxes can offer relevant opportunities, particularly for innovation and growth, and especially for SMEs, micro-enterprises and start-ups. This is consistent with Conclusion Number 2, in which the Council states that, in order for the EU to emerge stronger after the Covid-19 crisis, ‘the EU regulatory framework needs to be as competitive, effective, efficient, coherent, predictable, innovation-friendly, future-proof, sustainable and resilient as possible. It needs to be evidence-based and has to protect and support both citizens and businesses in the context of the

increase in the total amount of venture investment can be evidence that the regulatory sandboxes are functioning systematically as a practical deregulation device”; meanwhile, “the introduction of the regulatory sandboxes provides a policy effect that reduces legal and institutional risks by eliminating uncertainty through the adoption of flexible and inclusive business models in startups of the new industry, fintech. While governments support new industries with platforms and policies, they also play an essential role in the sustainability of innovation by providing business friendly regulations”.

155. J. Truby, R.D. Brown, I.A. Ibrahim, O. Caudevilla Parellada, *A sandbox approach to regulating high-risk artificial intelligence applications*, in *European Journal of Risk Regulation*, p. 290.

156. *Ibidem*.

aim of a fully functioning EU single market without imposing new unnecessary burdens and while reducing existing unnecessary burdens”¹⁵⁷.

Thus, the Council “clearly envisions that technological competition is essential to driving growth, and it recognises the need to eliminate barriers and burdens for firms”¹⁵⁸.

More recently, the European Union with the Communication of 21 April 2021, n. 206, put forward a “Proposal for a Regulation of the European Parliament and the Council laying down harmonized rules on artificial intelligence (artificial intelligence act) and amending certain Union legislative acts”¹⁵⁹.

The proposal expressly states that regulatory sandboxes could contribute “to the objective to create a legal framework that is innovation-friendly, future-proof and resilient to disruption. To that end, it encourages national competent authorities to set up regulatory sandboxes and sets a basic framework in terms of governance, supervision and liability. AI regulatory sandboxes establish a controlled environment to test innovative technologies for a limited time on the basis of a testing plan agreed with the competent authorities”¹⁶⁰.

This proposal also predicts that “AI regulatory sandboxes established by one or more Member States competent authorities or the European data protection supervisor shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance by the competent authorities with a view to ensuring compliance with the requirements of this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox”¹⁶¹.

157. *Ibidem*.

158. *Ibidem*.

159. European Commission, Commission Communication “Proposal for a Regulation of the European Parliament and the Council laying down harmonized rules on artificial intelligence (artificial intelligence act) and amending certain Union legislative acts”, 21 April 2021, n. 206. See M. Timoteo, B. Verri, W. Yukai, *Ethics Guidelines for Artificial Intelligence: Comparing the European and Chinese Approaches*, in *China and WTO Review*, 2021, p. 305 ss.; M. Rabitti, A. Sciarone Alibrandi, *La proposta di regolamento europeo sull'intelligenza artificiale nel prisma del settore finanziario: uno sguardo critico*, in M. Passalacqua (a cura di), *Diritti e mercati nella transizione economica e digitale. Studi dedicati a Mauro Giusti*, Padova, 2022, p. 469 ss.; G. Lo Sapio, *Intelligenza artificiale: rischi, modelli regolatori, metafore*, in *Federalismi.it*, 2022, p. 232 ss.; G. Finocchiaro, *The regulation of artificial intelligence*, in *AI&Society*, 2023, p. 1 ss.

160. European Commission, Commission Communication “Proposal for a Regulation of the European Parliament and the Council laying down harmonized rules on artificial intelligence (artificial intelligence act) and amending certain Union legislative acts”, 21 April 2021, n. 206, p. 15.

161. Article 53,1, European Commission, Commission Communication “Proposal for a Regulation of the European parliament and the Council laying down harmonized rules on

In this regard, it should be noted that “under Title V, Articles 53-55, 98 the EC proposal explicitly adds sandbox regulation to AI liability regulation within the EU”, specifying that “the idea of using a regulatory AI sandbox in the EU is not an entirely novel concept”¹⁶².

Moreover, the cited EC proposal was criticized by the doctrine highlighting three significant limitations: “The first two stem from its failure to address the need to balance liability protection and innovative experimentation for participants while in the sandbox and before market placement. First, the continued imposition of liability under Article 53(4) means that the sandbox only provides an exemption from regulatory compliance. While developers should not be allowed to use the sandbox as a shield to liability, imposing the same liability regime on sandbox participation could lead to limiting innovation”¹⁶³.

Second, “the EC Proposal’s Sandbox could create a false perception of safety and compliance in the market”, and, third, “the EC Proposal’s sandbox could lead to uncertainty and confusion in the market since it is not mandatory to, and not necessarily uniform among, EU states”¹⁶⁴.

Moreover, on this point, the European Union “appears to have chosen the pure strict liability approach, which could restrict innovation in the field of AI, and it applies the same approach in the sandbox environment [...]. In other words, the EU approach gives a nod to sandboxes, recognising their utility in fostering innovation, but with limited protection from potential liability. The EC Proposal holds AI sandbox participants liable and thereby creates a sandbox regulatory environment that remains subject to AI strict liability”¹⁶⁵.

Thus, the EC Proposal “would offer a lowered incentive for AI developers to participate in the sandbox since doing so would only subject the developer to the exposure of trade secrets and algorithms and added regulatory compliance,

artificial intelligence (artificial intelligence act) and amending certain Union legislative acts”, 21 April 2021, n. 206.

162. J. Truby, R.D. Brown, I.A. Ibrahim, O. Caudevilla Parellada, *A sandbox approach to regulating high-risk artificial intelligence applications*, in *European Journal of Risk Regulation*, p. 284.

163. Ivi, p. 286.

164. D.A. Zetsche, R.P. Buckley, J.N. Barberis, D. Arner, *Regulating a revolution: From regulatory sandboxes to smart regulation*, in *Fordham Journal of Corporate & Financial Law*, p. 286.

165. J. Truby, R.D. Brown, I.A. Ibrahim, O. Caudevilla Parellada, *A sandbox approach to regulating high-risk artificial intelligence applications*, in *European Journal of Risk Regulation*, p. 28, observe that “While liability exemption for regulatory sandboxes is not the norm even in FinTech, the lack of liability protection in AI sandboxes becomes more prominent because of the unlimited application of AI and its unforeseen risks, making liability testing even more important than regulatory compliance in AI sandboxes than in FinTech sandboxes”.

without the benefit of a moratorium on strict liability. In this way, the AI sandbox may inadvertently lead to stifling innovation. In other words, the role of the sandbox in development, testing and validation is only for the purposes of regulatory compliance rather than to assess the AI innovation's exposure to potential liability"¹⁶⁶.

In conclusion, "in the foreseeable future, regulatory experiments that transcend both the country and industry boundary will take place more frequently, which begs the question of how legal liability and regulatory responsibility can be adequately allocated among the firms which conduct trials together. Regulatory experiments can be treated as the third type of collaborations"¹⁶⁷.

In conclusion, technological innovation relating to sandboxes could be extended to the industrial sector, particularly SMEs.

This would inaugurate a new relationship between public regulators and private individuals that "engaging actively and sensibly in broad-purpose" can "gradually enable an input-based approach and develop SupTech solutions, and then further utilize SupTech to turn these sandboxes into 'supervisory control boxes' and fulfill a collaborative data empowerment supervisory regime"¹⁶⁸.

Thus, the supervisory control box "symbolizes a new paradigm of technology-enabled self-regulation, which essentially allows sandbox members to regulate themselves through a collaboratively designed and maintained governance framework. In the control box, regulators facilitate (but do not dominate) the crafting of an effective governance framework, set common standards for regulatory reporting data sharing, develop SupTech solutions, and apply them to sandbox members to gather user feedback"¹⁶⁹.

166. *Ibidem*, specify that "in reality an AI system could meet regulatory compliance but could lead to unforeseen liability risks, or it could evolve into a high-risk AI through unanticipated applications. The EC Proposal's sandbox essentially only offers a limited timeframe in which to determine AI innovations' regulatory compliance before market placement. According to Article 53 of the EC Proposal, one or more EU states may establish an AI regulatory sandbox, thereby allowing for different sandbox frameworks and implementations. These various AI sandboxes need to coordinate and cooperate with the European Artificial Intelligence Board and set out implementing acts, which will later lead to common implementing rules and frameworks. Yordanova remains cautious about the applicability of an AI regulatory sandbox in the EU when it remains unclear how a national regulator can fully participate in a regulatory sandbox when the area of regulation falls partly or entirely under EU's competencies".

167. C.Y. Tsang, *From industry sandbox to supervisory control box: Rethinking the role of regulators in the Era of Fintech*, in *Journal of Law, Technology & Policy*, 2019, p. 360.

168. Ivi, p. 395.

169. Ivi, p. 397.

4. Conclusion. The central role of SMEs in the European economy. From the small business act to a digital small business act

This study analyses the production sector of SMEs from the perspective of public regulations in Europe.

The analysis highlights several issues that can help build an innovative new framework for small enterprises within the broader scope of digital regulation and offers a new perspective relevant to the overall economic context.

It is important to emphasize that European legislators and regulators can no longer ignore the economic and social changes caused by the Covid-19 pandemic and recent geopolitical conflicts.

These events will profoundly affect the economy and society.

This study examines how some processes that are already underway, such as digitization, will radically affect SMEs.

Smaller companies will have to operate within a production environment that is vastly different from the one in which they have traditionally operated.

Given this, it is up to the legislative and the regulatory authorities to find both regulatory and normative solutions.

Therefore, the values contained within the UN's ESG goals have much broader cultural significance today in terms of affecting market regulation.

For example, the Green Deal Industrial Plan for the Net-Zero Age, presented by the European Commission (EC) on February 1, 2023 (in Communication n. 62), states, "This decade will be decisive for the world to limit the rise in global temperatures and to take the necessary steps towards net-zero. The stakes are high and the challenges complex, but there is a once-in-a-generation opportunity to use this imperative to act as a catalyst to invest in the clean energy economy and industry of the net-zero age".

The European Green Deal "sets in stone our green transition ambitions, including our climate targets towards net zero by 2050. The Fit for 55 package provides a concrete plan to put the European economy firmly on track, with the REPowerEU Plan accelerating the move away from fossil fuels. Alongside the

Circular Economy Action Plan, this sets the framework for the transformation of the EU's industry for the net-zero age"¹.

Over the next few years, "the economic shape of the net-zero age will be firmly set. New markets will have been created, breakthrough clean technologies will have been innovated, developed, and brought to market, and our energy systems will have been transformed. Therefore, those who invest first and faster today will secure their place in this new economy and create jobs for a newly skilled workforce, rejuvenate industrial manufacturing bases, lower costs for people and businesses, and be in a prime position to support other parts of the world to decarbonise their own economies. The scale of the opportunity for European industry puts this need in sharp focus"².

To meet these challenges, the European Union created a New Green Deal Industrial Plan that "will form part of the European Green Deal, which set us on the path to climate neutrality and will enable Europe to lead the way globally in the net-zero industrial age"³.

The new plan will "massively increase the technological development, manufacturing production and installation of net-zero products and energy supply in the next decade, and the value added of an EU-wide approach to meet this challenge together", will complement "ongoing efforts to transform industry under the European Green Deal and the EU Industrial strategy, in particular the Circular Economy Action Plan. Modernising and decarbonising energy-intensive industries also remain a top priority, as does ensuring job transitions and quality job creation through training and education"⁴.

The Green Deal Industrial Plan is based on four pillars, namely, a simplified regulatory environment, faster access to sufficient funding, skills, and open trade to support resilient supply chains⁵.

While all of these pillars are relevant and inherently interconnected, the first is a central point that could have a substantial effect on small and mid-sized companies.

SMEs need a legal framework and regulations that enhance their productive and commercial potential. Even more importantly, they depend on a "predictable, coherent and simplified regulatory environment"⁶.

1. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee, and the Committee of the Regions, A Green Deal Industrial Plan for The Net-Zero Age, 1 February 2023, n. 62, p. 1.

2. *Ibidem*.

3. Ivi, p. 3.

4. *Ibidem*.

5. *Ibidem*.

6. *Ibidem*. Regarding regulatory and administrative simplification, it is worth mentioning an

Also, “The EU has traditionally relied on a strong regulatory environment for setting conducive conditions for business, for providing quality employment for our workforce and a high level of protection for our environment”. These three dimensions “can be mutually reinforcing if regulation is balanced and smartly designed, which requires continuous attention”⁷.

Therefore, the Commission “has introduced an additional “competitiveness check” on all new regulations to ensure that all potential competitiveness impacts are addressed, and unnecessary burdens avoided. A simple, predictable, and clear regulatory environment is key to promoting investment”⁸.

It is not easy to prevent “fragmentation between 27 regulatory approaches” in legal, political, and economic terms. Therefore, in 2023, the Commission “will table three key proposals for industrial competitiveness, rooted in the need for reform”. The first key proposal is “to put forward a Net-Zero Industry Act to underpin industrial manufacturing of key technologies in the EU”. This “would provide a simplified regulatory framework for a production capacity of products that are key to meet our climate neutrality goals, such as batteries, windmills, heat pumps, solar, electrolyzers, carbon capture, and storage technologies”⁹.

From a regulatory perspective, after identifying “goals for industrial

instrument set up by the European Commission precisely for this purpose. Reference is made to the Fit for the Future Platform, part of the Refit Programme, which has the task of assisting the Commission with regulatory simplification and the reduction of administrative burdens. Commission Decision of 11 May 2020, establishing the Fit for Future Platform (2020/C 163/03), the Platform “should consider the efficiency of Union legislation, also addressing legislative density. It should look for evidence on additional burdens coming from the implementation of Union legislation in the Member States, to the extent possible” (Whereas 11), and “should provide evidence-based opinions on the topics identified in the annual work programme and reply to any Commission request for information and evidence on issues related to its better regulation work within the REFIT programme” (Whereas 13). Regarding SMEs, the Platform will “help identify the policy areas and legislation, including, when relevant, delegated, and implementing acts, where there are indications of unnecessary costs for business and citizens stemming from Union legislation. The EU SME Envoy will provide advice and input in particular in relation to the burdens and complexity of legislation affecting small and medium-sized enterprises” (Whereas 10).

7. Ivi, p. 4.

8. *Ibidem*.

9. *Ibidem*, states that “The Net-Zero Industry Act would in particular, following sector-specific analysis, identify goals for industrial capacity by 2030 where necessary to ensure that strategic dependencies do not put the green transition at risk. It will consider the whole supply and value chain across borders so that supplies do not become a bottleneck, reduce the length and enhance the predictability of permitting processes by defining specific time limits for different stages of permitting, and significantly reinforce Member States’ administrative capacity, e.g., by introducing a “one-stop-shop”: a sole point of contact for investors and industry stakeholders during the entire administrative process”.

capacity by 2030 where necessary to ensure that strategic dependencies do not put the green transition at risk”, the Net-Zero Industry Act would reduce “the length and enhance the predictability of permitting processes by defining specific time limits for different stages of permitting, and significantly reinforce Member States’ administrative capacity, e.g., by introducing a ‘one-stop-shop’, a sole point of contact for investors and industry stakeholders during the entire administrative process”¹⁰.

The Communication points out that “European standards can help to promote the roll-out of clean and digital technologies. In particular, for new industrial value chains, anticipating and developing high-quality European standards could provide EU industries an important competitive advantage, including at the global level”. They could “demonstrate ‘marketability’ and attract investment in firms that adhere to them. European standards would allow EU industries to scale up their technologies across the Single Market, this is very important for start-ups and SMEs”¹¹.

The Act “could enable the Commission to request European standards promoting the fast roll-out of key technologies”¹².

In this context, the Commission also proposes to evaluate the possibility of establishing so-called Regulatory Sandboxes “to allow for rapid experimentation and disruptive innovation to test new technologies”¹³.

In this study, we point out that the potential and critical issues accompanying the experimentation done by Regulatory Sandboxes today could “also pave the way for the simplification of the process of authorization/certification for placing products in the market”. We note that “these procedures can now be lengthy, slowing the introduction of innovative products and representing a significant burden, especially for SMEs and start-ups. The Commission will continue funding testing facilities as one important step to bring technology to market”¹⁴.

The second key proposal of the Commission focuses on the Critical Raw Materials Act, as “the manufacturing of EU net-zero technologies is only possible if access to relevant critical raw materials is ensured, including by diversifying sourcing and by recycling raw materials to lower the EU’s dependence on highly concentrated supplies from third countries and boost quality jobs and growth in the circular economy”¹⁵.

10. *Ibidem*.

11. *Ibidem*.

12. *Ibidem*.

13. Ivi, p. 6.

14. Ivi, p. 5.

15. Ivi, p. 6.

The new Act aims “to provide the EU security of supply, including by strengthening international engagement, facilitating extraction (where relevant), processing and recycling, while ensuring high environmental standards and continuing research and innovation, e.g. to reduce material use and to develop bio-based substitutes. There have already been tangible successes: today, some EU companies are using lignin stemming from wood in batteries, instead of graphite”¹⁶.

The third proposal to be presented by the Commission is “a reform of the electricity market design, for which public consultation is currently ongoing. Long-term price contracts could play an important role to enable all electricity users to benefit from more predictable and lower costs of renewable power”¹⁷.

This is because, as the REPowerEU Plan states, “boosting industrial competitiveness will require both transforming industrial processes, massive speed-up and scale-up of renewable energy, and stronger efforts for energy efficiency and reduction of energy demand as well as reskilling and upskilling of the workforce”¹⁸.

Infrastructure will play a key role in Europe’s new zero net emission industrial plan, from an economic, legal, and regulatory point of view. Therefore, the Commission urges co-legislators “to adopt the Alternative Fuels Infrastructure Regulation (AFIR) as soon as possible, to help create a future-proof charging and refuelling network. To develop and strengthen hydrogen and electricity infrastructure, the Commission will further examine the resource needs of the Connecting Europe Facility and will use the full scope of the revised TEN-E Regulation to accelerate the planning, financing, and deployment of crucial (cross-border) infrastructure”¹⁹.

16. *Ibidem*.

17. *Ivi*, p. 7.

18. *Ibidem*, states that “The new EU regulatory framework for batteries is a crucial element in the EU’s transition to a climate-neutral economy, by securing competitive and resilient value chains for battery production, reuse and recycling in the EU. Going forward, the Eco design for Sustainable Products Regulation will apply to a broader range of products and further expand the range of sustainability requirements, in which the EU industry excels. The Commission will give a high priority to work on net-zero technologies under the existing and future Eco design working plans. Furthermore, it is key that consumers can make their choices based on transparent and reliable information on the sustainability, durability, and carbon footprint of the products. Market transparency is a tool facilitating the uptake of technologically and environmentally superior net-zero products. For example, the Commission will propose a unified energy label for heat pumps to allow users to compare different technologies by the end of this year. The Commission proposal on empowering consumers for the green transition also works in this direction”.

19. *Ibidem*, states that “Notably the development and implementation of the cross-border infrastructure needs to be accelerated in the coming years. The Commission will also consider further ways, including possible legislative action, to make sure that Member States deliver

Policies to enhance skills will be particularly important in the new regulatory proposals to be launched by the European Commission, especially for smaller companies, as “the green transition must be people-centered and inclusive to ensure equitable and just outcomes, generating quality jobs and leaving no one behind. The European economy counted 4.5 million green jobs in 2019 up from 3.2 million in 2000. The green transition will amplify demands for new skills at all levels, requiring a large-scale up-skilling and re-skilling of the workforce. The battery industry alone estimates it will need an extra 800,000 workers by 2025. In the next decade, there will be fierce competition for talent. The productivity of our industry, the prosperity of our society, and our ability to meet the net-zero objectives will depend on our ability to retain and attract workers”²⁰.

Therefore, “the third pillar of the Green Deal Industrial Plan must focus on skills, green and digital, at all levels and for all people, with the inclusiveness of women and youth at the heart of the Plan. Demand for talent is acute”²¹.

Furthermore, because the transitions are both green and digital, the challenge facing Europe’s industries cannot be met without a new “European Pact for Skills, which recently celebrated its second anniversary, supports large-scale partnerships in European industrial ecosystems helping them to equip the workforce with the skills necessary for the transition towards a carbon-neutral and digital economy. The partnerships promote coordinated action by companies, workers, public authorities, social partners, education and training providers, and employment services. Over 1,000 members have so far signed up, including large multinational companies, SMEs, local training providers, and chambers of commerce”²².

Moreover, the recent Communication on harnessing talents in Europe’s regions supports “policies to help acquire and develop the skills required for the green transition in all EU regions. The European Year of Skills 2023 is a unique opportunity to develop the skills needed to thrive in a rapidly changing economy and to step up efforts”²³.

cross-border energy infrastructure so that there are no undue delays to the roll-out of the strategic infrastructure. The Green Deal Industrial Plan will succeed in boosting competitiveness if all actors (authorities, social partners, investors, consumers) join forces towards the same objectives. The recently established Clean Tech Europe Platform, the Clean Energy Industrial Forum, together with other relevant stakeholders, would support the plan, coordinate action to meet the investment and manufacturing targets, and further promote matchmaking opportunities”.

20. Ivi, p. 14.

21. Ivi, p. 15.

22. *Ibidem*.

23. *Ibidem*, where initiatives for a European Strategy for Universities are proposed and the establishment of Net-Zero Industry Academies “to roll out up-skilling and re-skilling

In this regard, the issue of vocational retraining is transversal and has long been the subject of reflection and analysis by the European Commission. For example, in the 2030 Digital Compass: the European Way for the Digital Decade²⁴, published in 2021, states the urgency of achieving the objective of a digitally skilled population and highly skilled digital professionals, on the premise that “in the world of tomorrow, if we want to be the master of our own destiny, confident in our means, value, and choices, we must rely on digitally empowered and capable citizens, a digitally skilled workforce, and way more digital experts than today”²⁵.

This can be achieved “by the development of a high-performing digital education ecosystem, as well as by an effective policy to promote links with and attract talent from all over the globe. Digital skills will be essential to reinforce our collective resilience as a society. Basic digital skills for all citizens and the opportunity to acquire new specialised digital skills for the workforce are a prerequisite to participate actively in the Digital Decade, as explained in the European Skills Agenda”²⁶.

The Digital Compass will follow the EU’s trajectory of digital transformation, “to deliver the vision and set out key milestones along four cardinal points. The first two are focused on digital capacities in infrastructures and education & skills, and the two others are focused on the digital transformation of business and public services”²⁷.

Specifically with respect to digital transformation in businesses, the Digital Compass observes that “artificial intelligence, robotics and augmented reality will be at the core of new products, new manufacturing processes and new business models based on fair sharing of data in the data economy. In this

programmes in strategic industries for the green transition, such as raw materials, hydrogen, and solar technologies”.

24. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, Digital Compass: The European way for the Digital Decade, 9 March 2021, n. 118.

25. Ivi, p. 4.

26. Ivi, p. 5, states that “The European Pillar of Social Rights Action Plan projects the target for adults with at least basic digital skills to 80% in 2030. To allow all Europeans to fully benefit from the welfare brought by an inclusive digital society, and as proposed in the chapter on digital principles (Section 4), access to education allowing the acquisition of basic digital skills should be a right for all EU citizens and lifelong learning should become a reality. Broad-based digital skills should also build a society which can trust digital products and online services, identify disinformation and fraud attempts, protect itself against cyberattacks, scams and fraud online, and in which children learn how to understand and navigate through the myriad of information they are exposed to online”.

27. Ivi, p. 4.

context, the swift adoption and implementation of the Commission’s proposals for the Digital Single Market. An edge node is a computer that acts as an end-user portal (or “gateway”) for communication with other nodes in cluster computing, where components of a software system are shared among multiple computers²⁸.

Therefore, “Europe’s digital future strategies will enhance the digital transformation of businesses and ensure a fair and competitive digital economy. It will also need to be matched with a level playing field abroad. The transformation of businesses will depend on their ability to adopt new digital technologies rapidly and across the board, including in industrial and services ecosystems that are lagging. EU support, notably through the Single Market, Digital Europe, and Cohesion programmes, will promote the deployment and use of digital capabilities including industrial data spaces, computing power, open standards, testing, and experimentation facilities²⁹.”

Regarding the role SMEs play in digital transition, the Digital Compass states that “SMEs have a central role in this transition, not only because they represent the bulk of the EU companies, but also because they are a critical source of innovation²⁸. With the support of over 200 Digital Innovation Hubs and industrial clusters, by 2030 SMEs should have the opportunity to access digital technologies or data easily and on fair terms, ensured by appropriate regulation, and benefit from adequate support to digitalise. In this respect, more than 200 European Digital Innovation Hubs and industrial clusters across the EU should support the digital transformation of both innovative and non-digital SMEs and connect digital suppliers to local ecosystems. The objective is to achieve a high level of digital intensity, leaving no one behind. The Commission will update its Industrial Strategy, also to accelerate the digital transformation of the industrial ecosystems in support of the 2030 targets. It is our proposed level of ambition that by 2030, 75% of European enterprises [will] have taken up cloud computing services, big data, and Artificial Intelligence. More than 90% of European SMEs [will have] reach[ed] at least a basic level of digital intensity, Europe will grow the pipeline of its innovative scale-ups and improve their access to finance, leading to doubling the number of unicorns in Europe³⁰.”

Regarding the digitalization of public services, the European Commission states that “by 2030, the EU’s objective is to ensure that democratic life and

28. Ivi, p. 10, where it notes that intelligent edge computing applications “In Manufacturing-as-a-service enabling manufacturing companies – notably SMEs – to have local access to cloud-based innovative industrial services platforms, and marketplaces to boost the visibility of their production capacities”.

29. *Ibidem*.

30. *Ibidem*.

public services online will be fully accessible for everyone, including persons with disabilities, and [will] benefit from a best-in-class digital environment providing easy-to-use, efficient, and personalized services and tools with high security and privacy standards. Secured e-voting would encourage greater public participation in democratic life. User-friendly services will allow citizens of all ages and businesses of all sizes to influence the direction and outcomes of government activities more efficiently and improve public services. Government as a Platform, as a new way of building digital public services, will provide holistic and easy access to public services with a seamless interplay of advanced capabilities, such as data processing, AI, and virtual reality. It will also contribute to stimulating productivity gains by European business, thanks to more efficient services that are digital by default as well as a role model incentivizing business, in particular SMEs, towards greater digitalization”³¹.

On 15th December 2020, the Commission issued a Digital Package, composed of a Digital Markets Act (DMA Proposal)³² and a Digital Services Act (DSA Proposal)³³ that “would include one pillar aiming at deepening the internal market and clarifying the responsibilities of digital services”³⁴.

This is relevant to this study and the need to regulate the market for data in Europe with digital safe-space principles and fair competition.

31. *Ibidem*.

32. Proposal for a regulation of the European Parliament and of the Council on Contestable and Fair Markets in the Digital sector (Digital Markets Act), 15 December 2020, n. 842. On this proposal see, P. Manzini, *Unravelling the proposal of the Digital Market Act. La proposta di legge sul mercato digitale: una prima mappatura*, in *Orizzonti del diritto commerciale*, 2021, p. 435 ss.; P. Bergkamp, *The proposed EU Digital Markets Act: A New era for the Digital Economy in Europe*, in *European Company Law Journal*, 2021, p. 152 ss.; N. Petit, *The Proposed Digital Market Act (DMA): A Legal and Policy Review*, in *Journal of European Competition Law and Practice*, 2021, p. 529; M. Dietrich, T. Vinje, *The European Commission’s proposal for a Digital Markets Act. In search of a ‘golden standard’ for appropriate ex-ante regulation of large digital players*, in *Computer Law Review International*, 2021, p. 33 ss.

33. Proposal for a regulation of the European Parliament and of the Council on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31, 15 December 2021, n. 825. On this proposal see P. Van Cleynenbruegel, *The Commission’s digital services and Market’s Act proposal: First step towards tougher and more directly enforced Eu rules*, in *Maastricht Journal of European and Comparative Law*, 2021, p. 1 ss.; A. Bendiek, *The Impact of the Digital Services Act (DSA) and Digital Market Act (DMA) on European Integration Policy. Digital Market Regulation as one of five major digital Policy projects of the Eu*, SWP Working Paper, 2021, p. 3 ss.; A. Turrillazzi, F. Casolari, M. Taddeo, L. Floridi, *The Digital Services Act: An Analysis of its Ethical, Legal, and Social Implications*, in *Law, Innovation and Technology*, 2023, p. 1 ss.

34. S.B. Micova, A. de Streel, *Digital Services Act. Deepening the internal market and clarifying responsibilities for digital services*, Report CERRE – Centre on Regulation Europe, December 2020, p. 7.

These proposals, legally based on Article 114 of the Functioning of the European Union Treaty (TFEU), appear reductive compared to the initial drafts that envisaged a three-pillar regulatory proposal. The first involved the regulation of digital services via the Digital Services Act, the second relied on regulating digital markets via the Digital Markets Act, and the third focused on the so-called New Competition Tool³⁵.

This would have provided antitrust authorities with new tools to better respond to the characteristics of digital markets³⁶.

Although the creation of the new anti-competitive instrument subsequently failed³⁷, the Digital Package appears “as nothing less than the fundamental framework for the digital world. It contains tough obligations for large digital gatekeepers and has some idea on enforcement”³⁸. Rather, it has been defined as “a major cornerstone in the building [of] Europe’s digital future and strategy and constitutes the first major overhaul of the EU law regime in the digital sphere [in] two decades”³⁹.

With these proposals, the European Commission intended to create a single

35. M. Broadbent, *The Digital Services Act, the Digital Markets Act, and the New Competition Tools*. European Initiative to Hobble U.S. Companies, Center for Strategic and International Studies, 2020, p. 1 ss.

36. G. Contaldi, *Il DMA (Digital Market Act) tra tutela della concorrenza e protezione dei dati personali*, in *Ordine internazionale e diritti umani*, 2021, p. 292.

37. *Ibidem*.

38. R. Podzun, P. Bongartz, S. Langenstein, *The Digital Market Act: Moving from competition Law to Regulation for Large Gatekeepers*, in *Eu COM*, 2021, p. 60, which states that, “in proposing DMA, the Commission reacts to challenges posed by the business practices of online platforms. Platforms connect distinct customer groups in multisided markets. They share a set of characteristics. Firstly, the service offered by a platform is intermediation. It provides a forum, where economic actors meet in search of each other. The platform’s added value is the reduction of search costs by coordinating its users’ behavior and selecting from an oversupply of information. Secondly, the intermediation service is targeted at matching the platform users in a marketplace scenario... Lastly, intermediation services are heavily dependent on information. The coordination of supply and demand reduces search costs to the lowest when the platform relies on data representing the entire market. On this account, platforms collect and process vast amounts of data”.

39. M. Dietrich, T. Vinje, *The European Commission’s proposal for a Digital Markets Act. In search of a “golden standard” for appropriate ex-ante regulation of large digital players*, in *Computer Law Review International*, 2021, p. 34, states how “Digital transformation and the emergence of the digital business model have brought about significant changes to markets offline and online... Today a small number of global companies largely control the flow of data around the globe, which helps them to capture a large share of the value generated in the digital sector via their platform. The debate about how to ensure competition in digital markets and guarantee “fair” market outcomes is a global one. Jurisdictions around the world are grappling with how to handle the digital market – including the complex issue of whether and how to regulate such markets without stifling innovation and overall consumer welfare” (p. 33).

EU-wide regulatory apparatus that would make the digital space more open and secure while respecting fundamental values and principles that would apply to the European Union⁴⁰.

The two proposals aimed to increase European innovation and competitiveness and to curb the overwhelming power of those few private IT giants, the so-called Big Tech.

We observe that “the Digital Services and Markets Acts contain different sets of rules. The Digital Services Act constitutes an update of and complements the e-commerce directive 2000/31. It primarily aims to clarify intermediary services providers [...]. The Digital Market Act targets those large actors that have a gatekeeper role and are or could, on relatively short notice, become (super) dominant enterprises. Since EU competition law can intervene only when harmful activities have taken place already, the DMA purposes the adoption of a regulation that will impose clear behavioral obligations, even without proven anti-competitive behavior”⁴¹.

The Digital Markets Act proposal changes “the paradigm for the regulation of online intermediaries in the EU, in that they put in place a single rulebook with a comparable approach to the frameworks already introduced for financial institutions, or for utilities such as energy, transport, and telecommunications. What these sectors and platform economy have in common is their systemic role in our economies and societies, creating major dependencies and risks to the functioning of the digital market”⁴².

In contrast, the Digital Services Act “aims to regulate the way that providers of online intermediary services interact with their customers and users, and their obligations in respect of harmful or illegal content”⁴³.

In general, the Digital Markets Act proposal proposes to primarily regulate the functioning of digital markets that “represent a particular commercial structure, which has so far made their regulation through traditional antitrust instruments problematic”. In this context, the aim was to “contain the domination of the

40. N. Zorzi Giustiniani, *Governing the ungoverned. Recenti proposte europee e internazionali per regolare il digitale*, in *Nomos*, 2020, p. 1. See P. Manzini, *Il Digital Market Act decodificato*, in M. Vellano, P. Manzini (a cura di), *Unione Europea 2020. I dodici mesi che hanno segnato l'integrazione europea*, Milano, 2021.

41. P. Van Cleynenbruegel, *The Commission's Digital Services and Markets Act Proposal: First Step Toward Tougher and More Directly Enforced EU Rules*, in *The Maastricht Journal of European Comparative Law*, 2021, p. 3.

42. F. Chirico, *Digital Markets Acts: A Regulatory Perspective*, in *The Journal of European Competition Law and Practice*, 2021, p. 493.

43. D. Savova, A. Mikes, K. Cannon, *The proposal for an EU Digital Service Act. A closer look from a European and three national perspectives: France, UK and Germany*, in *Computer Law Review International*, 2021, p. 38.

big online platforms, particularly the American multinationals known by the acronym GAFA (Google, Apple, Facebook, and Amazon)”.

In fact, “DSA and DMA are one building block of a total of five major digital policy projects of European re-sovereignisation”⁴⁴.

The European legislator is “aware of the lack of effectiveness of antitrust remedies in digital markets”, and states that “this legislative proposal aims to anticipate the effect of restrictive measures by preparing a regulation applicable ex-ante”⁴⁵.

The Digital Package has been approved in the Regulation of the European Parliament and of the Council on Contestable and Fair Markets in the Digital Sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (Digital Markets Act), 14 September 2022 n. 1925, and in the Regulation of the European Parliament and of the Council, on a Single Market for Digital Services and amending directive 2000/31/EC (Digital Services Act), 19 October 2022, n. 2065.

The economic and legal relevance of these regulations is evident in that they outline a new system of rules aimed at regulating and making the European digital market more transparent and fairer.

The Digital Markets Act specifies that “when the undertaking providing core platform services is a medium-sized, small or micro enterprise, the assessment should carefully take into account whether such an undertaking would be able to substantially undermine the contestability of the core platform services since this Regulation primarily targets large undertakings with considerable economic power rather than medium-sized, small or micro enterprises” (Whereas 24).

The Digital Markets Act also states, “the Commission should publish online a link to the non-confidential summary of the report, as well as all other public information based on information obligations under this Regulation, in order to ensure accessibility of such information in a usable and comprehensive manner, in particular for small and medium enterprises (SMEs)” (Whereas 68).

Separately, in assessing the request that compliance with a specific obligation be included in Articles 5, 6, or 7, the EC stated that regulations “shall take into account, in particular, the impact of compliance with the specific obligation on the economic viability of the operation of the gatekeeper in the Union as well as on third parties, in particular SMEs and consumers” (Article 9,4). At the same

44. A. Bendiek, *The Impact of the Digital Services Act (DSA) and Digital Market Act (DMA) on European Integration Policy. Digital Market Regulation as one of five major digital Policy projects of the Eu*, p. 7.

45. G. Contaldi, *Il DMA (Digital Market Act) tra tutela della concorrenza e protezione dei dati personali*, in *Ordine internazionale e diritti umani*, p. 300.

time, the Commission stated that it would evaluate “whether the aims of this Regulation of ensuring contestable and fair markets have been achieved and assess the impact of this Regulation on business users, especially SMEs, and end users (Article 53,2)”.

This means that smaller companies will benefit, although they find that to avoid disproportionate burdens, specific regulatory references in Whereas 49 transparency reporting obligations “should not apply to providers that are micro or small enterprises as defined in Commission Recommendation 2003/361/EC and which are not very large online platforms within the meaning of this Regulation”. At the same time “to avoid disproportionate burdens, the additional obligations imposed under this Regulation on providers of online platforms, including platforms allowing consumers to conclude distance contracts with traders, should not apply to providers that qualify as micro or small enterprises as defined in Recommendation 2003/361/EC” (Whereas 57).

The European Commission also states, “In the interest of effectiveness and efficiency, the Commission should carry out a general evaluation of this Regulation. In particular, that general evaluation should address, inter alia, the scope of the services covered by this Regulation, the interplay with other legal acts, the impact of this Regulation on the functioning of the internal market, in particular regarding digital services, the implementation of codes of conduct, the obligation to designate a legal representative established in the Union, the effect of the obligations on small and micro enterprises, the effectiveness of the supervision and enforcement mechanism, and the impact on the right to freedom of expression and of information” (Whereas 150).

Article 15 states that providers of intermediary services shall “at least once a year clear, easily comprehensible reports on any content moderation that they engaged in during the relevant period”, but this obligation “shall not apply to providers of intermediary services that qualify as micro or small enterprises as defined in Recommendation 2003/361/EC and which are not very large online platforms within the meaning of Article 33 of this Regulation”.

Article 19 of the Digital Services Act states that “this Section, except for Article 24(3) thereof, shall not apply to providers of online platforms that qualify as micro or small enterprises as defined in Recommendation 2003/361/EC. This Section, except for Article 24(3) thereof, shall not apply to providers of online platforms that previously qualified for the status of a micro or small enterprise as defined in Recommendation 2003/361/EC during the 12 months following their loss of that status pursuant to Article 4(2) thereof, except when they are very large online platforms in accordance with Article 33,2. By derogation from paragraph 1 of this Article, this Section shall apply to providers of online platforms that have been designated as very large online platforms in

accordance with Article 33, irrespective of whether they qualify as micro or small enterprises”.

Regarding Section 4 of the Digital Services Act, entitled “Additional provisions applicable to providers of online platforms allowing consumers to conclude distance contracts with traders”, the Regulation states that these provisions “shall not apply to providers of online platforms allowing consumers to conclude distance contracts with traders that qualify as micro or small enterprises as defined in Recommendation 2003/361/EC” (Article 29,1).

In addition, Article 91,1 of the Regulation specifies that “by 18 February 2027, the Commission shall evaluate and report to the European Parliament, the Council, and the European Economic and Social Committee on the potential effect of this Regulation on the development and Economic growth of small- and medium-sized enterprises” (see also Articles 91,2 and 91,6).

For our study, note that even in connection with the provisions mentioned above, the Digital Markets Act and the Digital Services Act contain regulatory provisions that are at least capable of enabling SMEs to participate in the data market.

Small businesses are one of the main economic actors that need protection, as defined in a proposed regulation from the European Parliament and the Council on contestable and fair markets in the digital sector (Digital Markets Act)⁴⁶, which notes that “whereas over 10,000 online platforms operate in Europe’s digital economy, most of which are SMEs, a small number of large online platforms capture the biggest share of the overall value generated”⁴⁷.

However, it is difficult to build an innovative regulatory framework that is responsive to the needs of SMEs and consistent with the Joint Declarations of the European Parliament, the Council, and the European Commission, On Digital rights and principles for the digital decade (2023/c 23/01), which affirms that the EU “puts people at the centre, empowers individuals and fosters innovative businesses” (Whereas 6).

This decision “sets out the concrete digital targets based on four cardinal points (digital skills, digital infrastructures, digitalisation of businesses, and public services). The EU’s way for the digital transformation of our societies and economy encompasses digital sovereignty in an open manner, respect for fundamental rights, rule of law and democracy, inclusion, accessibility, equality, sustainability, resilience, security, improving quality of life, the availability of

46. The Proposal of 15 December 2020 for a Regulation of the European Parliament and of the Council on fair and contestable markets in the digital area (Digital Markets Act), 15 December 2020, n. 842, p. 1.

47. *Ibidem*.

services, and respect for everyone's rights and aspirations. It should contribute to a dynamic, resource-efficient, and fair economy and society in the EU". It states that small businesses "should also serve as a reference point for businesses and other relevant actors when developing and deploying new technologies. Promoting research and innovation is important in this respect. Special attention should also be given to SMEs and start-ups" (Whereas 6).

Based on this, an effective regulatory framework for SMEs must have an equitable digital environment wherein "everyone should be able to effectively and freely choose which online services to use, based on objective, transparent, easily accessible, and reliable information. Everyone should have the possibility to compete fairly and innovate in the digital environment. This should also benefit businesses, including SMEs" (Chapter III)⁴⁸.

With respect to constructing a fair digital environment for businesses, recent legal studies have focused on an analysis of public administration based on new models of coordination and cooperation between regulated and regulating entities to build a "welcoming administration"⁴⁹ that is attentive to the continuous technological and digital innovations that businesses experience. This is known as an "Anticipatory Regulation", which is the subject of much scholarly debate⁵⁰ and has been defined as "an approach to regulation that provides a set of behaviors and tools – i.e., a way of working – that is intended to help regulators identify, build and test solutions to emerging challenges"⁵¹.

The central point of this new organizational model of public administration for the digital marketplace is the attempt by regulators to "work in a more

48. Joint Declarations of the European Parliament, the Council, and the European Commission, on Digital rights and principles for the digital decade (2023/c 23/01), resuming the European commitment to "a) ensuring a safe and secure digital environment based on fair competition, where fundamental rights are protected, users rights and consumer protection in the Digital Single Market are ensured, and responsibilities of platforms, especially large players and gatekeepers, are well defined; b) promoting interoperability, transparency, open technologies, and standards as a way to further strengthen trust in technology as well as consumers' ability to make autonomous and informed choices".

49. F. Vella, *Crescere sui mercati e piattaforme: le piccole medie imprese tra regole e politica industriale*, in *Mercato concorrenza regole*, 2019, p. 265.

50. See A. Taeihagh, M. Ramesh, M. Howlett, *Assessing the regulatory challenges of emerging disruptive technologies*, in *Regulation and Governance*, 2021, p. 1009 ss.; H. Armstrong, C. Gorst, J. Rae, *Renewing regulation. Anticipatory Regulation in an Age of Disruption*, Nesta Foundation, 2019; S. Gunashekar, S. Parks, *Oversight of emerging science and technology: Learning from past and present efforts around the world*, RAND Europe, 2019; M.K. Kolacz, A. Quintavalla, O. Yalnazov, *Who should regulate disruptive technology?*, in *European Journal of Risk Regulation*, 2019, p. 1 ss.

51. H. Armstrong, C. Gorst, J. Rae, *Renewing regulation. Anticipatory Regulation in an Age of Disruption*, p. 19.

anticipatory way”. In this context, the purpose of anticipatory regulation “is to better understand what the impacts of an emerging technology (which may not be developed enough for use) might be on the economy and society and, therefore, what the potential regulatory needs will be”⁵².

Anticipatory regulation differs from other regulatory approaches such as “advisory” or “adaptive” regulation, where “meaning regulators have to deal with more uncertainty, less evidence, and a greater number of possible risks. Here, the regulator is not only playing a more active role in supporting innovation but also in building an information and evidence base via direct research activities”⁵³.

Advisory regulation is designed “to make it easier for businesses with new products or services to approach regulators and work with them to test and then adapt the product or service under existing regulations. Innovators benefit from temporary relaxations in the full regulatory regime to test the potential impacts of their products or services, but the final goal is to fit within existing regulations. The regulator can play a more proactive, engaged role in the development and testing of innovations in that sector”⁵⁴.

Adaptive regulation is “employed when a regulator wants to help facilitate the development of new products or services, but existing regulatory frameworks may have to be adapted to do so. In this case, the objective is to first understand the value of these new products or services better by testing them in a restricted environment, then work to adapt both the innovation and/or existing regulations to bring the product or service to market. As with advisory approaches, participants are given regular advice and granted temporary regulatory relaxations. Unlike the advisory approach, if necessary regulatory barriers are identified, then permanent changes to the existing regulations can be explored, generally on a case-by-case basis”⁵⁵.

A central feature of anticipatory regulation is that the public regulator is equipping itself with new capabilities to address areas of regulatory risk, enabling them to manage the associated risks by making the most of the opportunities and potential inherent in new digital technologies that are entering the market, based on the assumption that *sate time* differs from *market time*⁵⁶.

Recent studies show that anticipatory regulation is based on six key principles that “represent the vital elements of a regulatory system that enables,

52. Ivi, p. 20.

53. *Ibidem*.

54. *Ibidem*.

55. *Ibidem*.

56. See U. Morera, M. De Poli (a cura di), *La rilevanza del tempo nel diritto bancario e finanziario*, Torino, 2018.

or stimulates, innovation for the public good in a timely and proactive way, while also protecting the public against harm and creating better markets”, and that “respond to emerging challenges presented in this paper and deliver value for the economy, society, and the environment, regulators need to start working in a more anticipatory way, embedding these principles into the way they work”⁵⁷.

The six principles are *Collaborative*, *Future-facing*, *Proactive*, *Iterative*, *Outcome-based*, and *Experimental*.

The first, *Collaborative*, is made up of two elements: first, “better engagement with a wider set of stakeholders, including the public, companies, innovators, NGOs, city authorities, local government, and other regulators, around emerging issues or the potential impacts of regulation. Contributions from all these actors will help shape better policies and regulations, particularly given the wide-ranging implications and ethical issues, surrounding next-generation technologies like AI and gene editing systems”. At the same time, the collaborative principle notes that “one of the biggest risks in deploying these technologies is to attempt to bypass public engagement and legitimation, the public reaction to GM crops is an obvious example of where this has gone wrong. Inclusivity helps generate solutions to problems that don’t respond well to traditional regulatory approaches or reliance on exclusive reliance on market forces, for example, consumer disengagement”⁵⁸.

The second principle, *Future-facing*, characterizes the approach of Anticipatory Regulation that “One of the biggest challenges regulators face is the inherent uncertainty associated with future developments in technology, changing markets, economic developments and shifts in society”: on this basis “All these factors impact what regulators might need to regulate (or not), the mechanisms they use and how appropriate existing or new regulation might be in the future. While it is not possible to predict what the future will be like, it is important to understand how things are changing and what kinds of futures these changes could create”⁵⁹.

In this context “the value of doing this is to develop more resilient strategies, policies, or regulations in the face of this uncertainty” by considering “three important elements of being future-facing: firstly, identifying what is changing in the world through what is often called ‘horizon or environmental scanning’; secondly, exploring the potential impacts of that change, for example, what

57. H. Armstrong, C. Gorst, J. Rae, *Renewing regulation. Anticipatory Regulation in an Age of Disruption*, p. 19.

58. Ivi, p. 20.

59. Ivi, p. 24.

impact might driverless cars have on liability or on the way people use cars; lastly, looking at how different changes or impacts of change might interact to create different situations (often called scenarios)”⁶⁰.

The third principle, *Proactive*, refers to a specific modus operandi a public regulator must assume to respond effectively to problems that may arise in the market, i.e., “actively engaging with innovators and innovations early to track emerging issues, assess possible opportunities, and define positive outcomes”⁶¹.

Of course, it is not easy to identify the best, most effective way of being proactive, as there are “several ways in which regulators can and do play a more proactive role in the innovation ecosystem”. Among these, “openness and accessibility” are of fundamental importance, as “for businesses, particularly smaller organizations who do not have existing links, regulators can feel like unapproachable agencies, only there to stop activities rather than support novel initiatives”. A public regulator can be proactive by creating “advice centers (sometimes called Innovation Hubs), one-stop shops, and better routes to engaging the relevant regulators, [which] have helped to break down perceived barriers. This not only helps businesses reach out sooner so they can seek support navigating the regulatory landscape, but it also means regulators get sight of new business models and innovations in a timely manner”⁶².

Furthermore, a public regulator can use the approach of “opening up data as a tool for driving competition and potentially seeding innovation elsewhere. Open banking reform in the UK [...] is a good example of this but much more could be done. Data sets that regulators already hold and their ability to require companies to make certain types of data available can create plenty of downstream value, for example, as a way of reducing the dominance of the big platform companies or allowing consumers more control over their data”.

The *Iterative principle* refers to a flexible, iterative learning approach that is necessary to adopt instead of “a solve-and-leave mentality, when regulators have to take on new functions for which they lack an established playbook or need to deal with uncertain market developments” or when “regulations are being developed for a new area or introduce substantial changes, it is difficult to know exactly what the impacts will be”. Using “a more experimental, trial and error approach, at least at the beginning, rather than immediately creating definitive rules can help build evidence on what works to achieve the desired outcomes”. Sandboxes, which are analyzed in this study, are among the most experimental and innovative approaches that can be ascribed to the Iterative

60. *Ibidem*.

61. *Ibidem*.

62. Ivi, p. 25.

principle. The standards, the “testbeds or exhorting best practice are different ways in which regulators can provide more flexible interventions. Using sunset clauses and defined points of review can also help identify when and how existing regulations may need to be revisited to achieve their existing or new goals in a changing environment. They can also add some regulatory certainty to the process as stakeholders would know when regulation may be adapted. If sunset or review clauses are going to be used, however, it is important that the review is thorough and well-resourced, employing the principles we have set out here. Here again, there is a need for better guidance on where and when different approaches, from standards to sandboxes, are most appropriate”⁶³.

The fifth principle of anticipatory regulation is *Outcome-based*, which holds that given “the disadvantages of command-and-control regulation in dynamic markets, regulators should focus on defining desired outcomes, agreeing on measures of success, and validating regulated organisations’ efforts to achieve them (and resisting pressures to increase regulatory prescription)” [and] “Moving towards outcomes rather than rules-based regulation can have a number of advantages while spurring innovation in the way regulated firms respond to deliver these outcomes”⁶⁴.

Applying this principle to the market “can help reduce the scope for firms to game or ‘creatively comply’ with set rules and focusing on outcomes is more resistant to the impacts of change compared to rules-based regulation. This approach is particularly relevant in areas where there is the potential for widespread technological disruption or systematic change in the way services are delivered”⁶⁵.

Lastly, the sixth principle of anticipatory regulation, *Experimental*, is applied when “top-down, whole-market regulation is ineffective, when sectoral barriers erode, barriers to entry are low, and the impact of emerging problems or opportunities is different in different contexts”. In these cases, the public regulator needs “to facilitate diverse responses by companies and others to test new innovations or regulatory interventions and build knowledge around possible impacts”⁶⁶.

These new regulatory experiments are of great interest to scholars of economic law as they are based on a new vision of the future of markets and new forms of entrepreneurship and focus on the consumer as an individual.

Realistically, any reflection will have to stem from a new vision of the

63. Ivi, p. 27.

64. *Ibidem*.

65. *Ibidem*.

66. Ivi, p. 29.

market and society, a vision such as the one outlined by the European Union, as we described above.

This involves an urgent need to rethink the regulatory function from a completely new technological/digital perspective, referred to as RegTech, thus facilitating relationships with regulated parties and reducing compliance costs⁶⁷.

It has been observed that “Ours is an era of technological innovation” for which “our law, then, must be tailored to the everchanging condition of life”⁶⁸.

Changes imposed by technological innovations are such that “in the diagnosis of this threat, much recent attention has been paid to the need for regulation, in recognition that existing systems are not equipped to tackle developments online”⁶⁹.

Others have emphasized that “the practice of regulation is often neglected in debates around regulatory change and reform within the current regulatory environment, and questions remain around the role of technology in regulation, compliance, and digital transformation. These questions are related to the role of RegTech in supporting the process of transition and providing the basis of a system to address its requirements; furthermore, they monitor compliance and support the achievement of regulatory and policy objectives by regulators and policymakers”⁷⁰.

As we have discussed in this study, supervisory functions are likely to become increasingly automated and digitized.

This will lead to the development of new types of digital Sup Tech and even Policy Tech.

It will also be interesting to observe how technological and digital developments will affect regulatory processes and experimentation in this area.

In drawing some conclusions from this study, it is clear the digital dimension will influence the development of future legal regulation for smaller companies.

This should improve the sometimes-weak links between public and private entities.

In other words, the digital dimension could constitute the common technological and information base on which to fundamentally rethink the

67. F. Vella, *Crescere sui mercati e piattaforme: le piccole medie imprese tra regole e politica industriale*, in *Mercato concorrenza regole*, p. 265.

68. M.K. Kolacz, A. Quintavalla, O. Yalnazov, *Who should regulate disruptive technology?*, in *European Journal of Risk Regulation*, p. 4.

69. K. Dommet, *Introduction: Regulation and Oversight of Digital Campaigning- Problems and Solutions*, in *The Political Quarterly*, 2020, p. 705.

70. See R.P. Buckley, W.A. Douglas, D.A Zetzsche., R.H. Weber, *The road to RegTech: the (astonishing) example of the European Union*, in *Journal of Banking Regulation*, 2020, p. 27.

role that smaller companies can play in the new European and international economic contexts.

SMEs are, in a way, the litmus test of the true effectiveness of economic policies and legal rules designed for businesses, especially when we consider their absolute relevance in both micro and macroeconomic terms.

Moreover, the technological challenges for smaller companies are so great that the European Union will have to make a significant, ongoing effort to allow them to participate in an economic recovery.

For this to happen, SMEs must have access to and an understanding of modern digital tools or they will struggle to survive.

In our opinion, a proper digitization process must start with digital education for entrepreneurs, who will need to learn about and understand the new digital tools that are used in the new digital marketplace and digital trading.

To facilitate this, European trade policy will have to be reviewed and rethought with a view toward technological innovation.

The European Commission shows it is aware of this issue when it reiterates that “the EU’s long-term competitiveness, prosperity, and global position will depend on its ability to embrace and harness the digital transformation. The green and digital transitions should therefore be a key priority for multilateral and bilateral trade policy. For the EU to retain and enhance its influence in shaping the rules necessary in this respect, it needs to develop a more strategic approach to international regulatory cooperation. This calls for closer policy integration between trade policies and internal EU policies”⁷¹.

The Commission is also aware that “the digital sphere will see an intense global competition that will reconfigure global economic relations. The EU can only succeed in its digital transformation if it builds its digital agenda in an outward-looking manner, taking full account of a global environment that is increasingly, fiercely competitive, and sometimes challenging the EU’s values-based approach to digitalization”. In this new scenario, “Trade policy will play a vital role in attaining the EU’s objectives linked to the digital transition. European businesses rely on digital services, and this will only increase. Data are the lifeline of many businesses and a critical component of the EU’s supply chains. Digital technologies provide efficiency gains, which are needed to remain competitive, but are also transforming traditional industrial sectors where European companies will need to maintain and boost their competitive position. At the same time, the digital transformation and emergence of new

71. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions, Trade Policy Review. An Open, Sustainable and Assertive Trade Policy, 18 February 2021, n. 66, p. 10.

technologies have an important security and values dimension for Europe and require a carefully calibrated policy approach internally and externally. The implications of new digital technologies, including artificial intelligence, need to be addressed globally through more ambitious global standards and rules. Supporting Europe's digital agenda is a priority for EU trade policy. The objective is to ensure a leading position for the EU in digital trade and the area of technology, most importantly by promoting innovation"⁷².

Having reached this point in our study, and by way of conclusion, we can say that today the overall situation of SMEs in the European Union is precarious but central to the area's economy.

There is no doubt that among the many challenges in this arena is the urgent need to define an innovative industrial policy aimed at building a new role for smaller enterprises to play in expanding Europe's digital economy and forming new opportunities for digital entrepreneurship within smaller enterprises⁷³.

In constructing a new industrial policy there must be awareness that SMEs not only play a key economic role but also represent a vector of fundamental importance in conveying the new cultural and environmental values brought forward by the European Union. Therefore, because of their widespread presence throughout the EU, SMEs could become a meeting point between the market and society.

72. Ivi, p. 15, "The EU should continue to lead the way in digital standards and regulatory approaches, in particular as regards data protection, where the EU's General Data Protection Regulation is often seen as a source of inspiration. To achieve this, the WTO needs to set the rules for digital trade and the EU needs to play a central role in creating them. Once they have been agreed, the EU should support further plurilateral WTO negotiations to liberalise trade in services in sectors going beyond e-commerce. The EU will also need to step up bilateral engagement and explore stronger frameworks for cooperation on trade-related digital issues with like-minded partners. It will seek to deepen its regulatory dialogues with like-minded partners".

73. On digital entrepreneurship see, J.M. Sahut, L. Iandoli, F. Teulon, *The Age of Digital Entrepreneurship*, in *Small Business Economy*, 2021, p. 1162, which observes that "We define DE as the process of entrepreneurial creation of digital value through the use of various socio-technical digital enablers to support effective acquisition, processing, distribution, and consumption of digital information", specifying that "this definition can be extended and applied to specific types of ventures such as nascent ventures and digital self-employment. For instance, some of these enablers can be used to support the very process of new venture creation, from idea generation and opportunity recognition to intellectual property protection, production, marketing, and distribution. Technologies such as social media, open-source software and hardware, crowdsourcing, crowdfunding, e-trust and online reputation assessment, 3D printing, digital imaging, and big data are empowering would-be entrepreneurs to significantly reduce the barriers between invention and the creation of a new company (Steininger 2019). The use of digital tools and platforms is favoring the emergence of a new type of job that is hard to classify unambiguously in the traditional categories of employment, self-employment, freelance, or growth-oriented entrepreneurial undertakings".

The relevance of SMEs is taken up and supported by Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021, which established the Recovery and Resilience Facility that underlines the recovery and resilience of the European Union and its member states in the face of serious negative economic and social impacts that have profoundly shaken the lives of European citizens.

This includes the structuring of public interventions defined by six pillars and establishes a prominent role for “smart, sustainable, and inclusive growth, including economic cohesion, jobs, productivity, competitiveness, research, development, and innovation, and a well-functioning internal market with strong small- and medium-sized enterprises (SMEs)” (Whereas 10 and Article 3,1), as well as planned reforms and investments that should promote the digitization of services, stating “the digital transition should also incentivize the digitalization of SMEs. Investments in digital technologies should respect the principles of interoperability, energy efficiency, and personal data protection, allow for the participation of SMEs and start-ups, and promote the use of open-source solutions” (Whereas 12).

This will require creating a new European legal framework to regulate the activities of SMEs in the market, which could lead to issue *specific Digital Small Business Act* that contains regulations for smaller companies with respect to the European digital market.

A single legal framework could help to realize the enormous potential of SMEs in the digital marketplace.

Public authorities and business activities need to discuss these new regulations.

They must build a dialogue built on mutual respect so that the size of a business does not affect its potential and should create digital legal regulations with anticipatory and predictive features in line with market dynamics.

The relationship between public administration and the subject administered and authority and freedom need rethinking. It should be centred and perfected on a solid and well-founded idea of dialectic between parties that regulate and operate in the market⁷⁴.

The adoption of a specific Digital Small Business Act will require the need for a *specific new digital regulatory dialogue* at a European level in which

74. R. Pini, *Divagazioni in margine al rapporto tra amministrati e amministratori (da un rapporto di regole a un rapporto di affezioni)*, Torino, 2021, p. 263. By the same author see R. Pini, *Democrazia bella. Democrazia incompiuta. Democrazia infranta*, Torino, 2019, and R. Pini, *Argomenti seminariali di diritto pubblico. Itinerari della Repubblica verso una società nuova*, Torino, 2023.

market regulators and enterprises have tools and skills to understand the technological innovations that characterise the activities of companies today.

A *specific new digital regulatory dialogue* that may encompass and collect all the most relevant experiences regarding digital public regulation issued by European Union member states.

Instead of a unilateral and bureaucratic administration, a new, participatory administration must listen to the interests involved before making decisions. Such an administration would operate on an equal footing with, and balance any barriers created by, legacy public administration by focusing on the real needs of the entities its actions affect⁷⁵.

In this new perspective, the dialog between public administration and business would heal the fracture between administrators and those administered.

This would improve communication by modifying the behavior of both parties and encouraging them to become genuine participants in activities aimed at satisfying general interests with a significant qualitative technical contribution⁷⁶.

In conclusion, the European legislator now has a unique opportunity to recognize and give SMEs genuine centrality within the digital world and the European economy.

In this context, SMEs can manifest their enormous economic and social potential by overcoming conceptual diffidence and legal obstacles that hinder this potential.

75. Ivi, p. 118.

76. Ivi, p. 274.

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