Digital spaces, Digital rules

Valedictory adresses by

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Understanding Society

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In 1995 he obtained his PhD ("Technical standards and law. Reflections on the interaction between law and technical standardisation in the field of information technology and telecommunications") at the Vrije Universiteit Amsterdam.

In 2001 he was appointed full professor "Information Technology Regulation" at Tilburg University.

His research and education activities were performed within the Institute for Law, Technology and Society (TILT) of the Tilburg Law School at Tilburg University. Next to his academic work he practised ICT law for nearly 30 years. He was admitted to the Amsterdam Bar from 1989. He is one of the founding partners of Kennedy Van der Laan and was a partner with PricewaterhouseCoopers/Landwell and Van Doorne (2004-2019).

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Prof. Dr. Kees Stuurman

Farewell speech
Delivered in shortened form by prof.dr. Kees Stuurman on June 29, 2022 in the auditorium of Tilburg University on the occasion of his farewell as professor of Information Technology Regulation at TILT, the Tilburg Institute for Law, Technology and Society at the Tilburg Law School.

ISBN 978-94-0367-447-6

www.tilburguniversity.edu/nl

Digital spaces, Digital rules

1 Introdution[1]

[1] The text of this booklet was finalized in August 2022.

Over the last 20 to 25 years a wave of digitization has had far-reaching influence on our society. We notice the consequences of these developments regardless of our capacity: consumer, citizen, parent, employee, student etc. Initially, this technological revolution seemed to bring a lot of new and exciting possibilities but gradually concerns about these developments have risen as well.

Twenty years ago the title of my inaugural address was 'Digital spaces, Analog rules'.[2] The title of today's valedictory address is 'Digital spaces, Digital rules'. This to reflect that we have moved from an 'analog world with digital impact' to 'digital as a parallel, connected universe'.

As of the mid 1990s the core of the EU regulatory approach to digitization has been formed. This provides an interesting timeline to reflect on – at least some aspects – thereof.

In this address I will in particular focus on the European digital regulatory framework that has emerged over the last 20/25 years and the role of technical standards in this framework.

When we return to the end of the 1990s, we could still see very modest use of computers and the Internet; the biggest challenge was the Y2K problem. Once we had overcome the challenge of the year 2000, there was a great prospect for the development of electronic commerce. With regard to digital regulations, the 1997 Distance Selling Directive[3] was a beacon, followed in 2000 by the well-known E-commerce Directive[4]. Important components of the latter directive were the rules on the liability of intermediaries and a number of rules on consumer protection (information duties).

In the Netherlands, the starting points for regulating the information society were laid down in the 1998 Report 'Wetgeving voor de elektronische snelweg' (Legislation for the electronic highway)[5] of the Ministry of Justice. Main starting point was that the development of the information society had to be facilitated primarily through self-regulation. This at least as long as there was technological

[2] Stuurman (2002)
[3] Directive 97/7/EC (currently no longer in force)
[4] Directive 2000/31/EC
[5] Tweede Kamer (House of Representatives), 1997–1998, 25880, nrs. 1–2

turbulence and no 'displacement' of traditional communication. Government action was in any case deemed appropriate when fundamental norms and values were at stake (such as the protection of citizens' classical fundamental rights and the prevention and investigation of serious breaches of the rule of law and state security).

I still consider this a masterpiece when it comes to the strategy for regulating the information society and in my view it still contains valuable elements for the discussions we are having today.

A lot has changed in the past 20 to 25 years. ICT and the ICT market have changed; everything is Internet based, in the cloud and powerful US platforms dominate large parts of the market. ICT has also become an integral part of all sectors in our society. This obviously also implies that a very broad spectrum of legislation is relevant for regulating the digital impact on our society.

In the next chapter I will focus on European digital policy making as the cradle for the development of the digital regulatory framework.

2 EU digital policy making

Table 1 - EU Digital policy milestones

- 2021 **Europe's Digital Decade** + EU 2030 **Digital Compass**

- 2020 **Shaping Europe's digital future**

- 2010 **Digital Agenda for Europe** (2010-2020)

- 2005 **i2010** - A European Information Society for growth and employment

-1999 **Lisbon Agenda** for 2010 / **eEurope** Action Plan

- 1994 **Bangemann report** ('Europe and the Global Information Society')

- 1993 **Delors White Paper** ('Information Society')

- 1985 Delors (ICT embedded in New Technologies)

European digital policy making has deployed a range of governance modes. Hereinafter I will focus on the regulatory mode (restricted to the drafting of directives and regulations)[6] and the use of standards and standardisation. Other tools applied by the European policymakers include the use of benchmarking, best practices and the use of trans governmental networks.[7]

In discussing the regulatory mode and the role of standardisation[8] I will use the recent initiative for a *European Health Data Space*[9] as a case study.

6 See the introduction of the Annex for further details.
7 Newman (2021), p. 289
8 The following description of the developments in the field of European digital policymaking is in particular based on Newman (2021) and Marcut (2017). See as well: Shahin et al (2009).
9 https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

How did it all start?[10]

The Delors European Commission took office in 1985. One of the main priorities was technological and industrial cooperation. Initially, ICT was positioned as part of a broad set of 'new technologies' ranging from telecommunication networks, to data processing software, to thermonuclear research and biotechnology.

In 1986 a Second Framework Program was adopted, containing eight major priorities, including the development of 'a large market and information and communications society'. This was essentially an amplification of the Esprit program[11] concerning electronics and information and the first time instance when the term 'information society' is explicitly used in Delors' tenure.[12]

The fact that we start our exploration in the year 1985 does not mean that no initiatives were taken in the preceding years. Already since the 1970s, digital policy-making was part of the broader EU agenda.[13]

In the early 1980s this became more tangible in terms of regulatory initiatives. This covered topics such as ICT related vocational training[14], data processing[15], telecommunications[16] and standardisation[17].

In the early 1990s, the 1993 'White Paper on Growth, Competitiveness and Employment: The Challenges and Ways Forward into the 21st Century'[18] of the Delors Commission constituted an important policy landmark. The title of the report shows that European policy makers were never shy of using big words.

In 1994 the White Paper was followed by the landmark Bangemann report, entitled 'Europe and the Global Information Society'.[19] The report, named after Michael Bangemann (the Commissioner for the Internal Market and Industrial

[10] See Marcut (2017), p. 13 ff. for more details regarding the achievements of the Delors Commission.
[11] For details see: https://en.wikipedia.org/wiki/European_Strategic_Programme_on_Research_in_Information_Technology_(ESPRIT)
[12] Marcut (2017), p. 24
[13] Newman (2021), p. 275
[14] European Union (1983)
[15] European Union (1984a)
[16] Including European Union (1984)
[17] European Union (1985)
[18] European Union (1993)
[19] European Union (1994)

Affairs), focused on the structural and systemic changes brought about the information society. These changes were treated in terms of a complete revolution changing the way we both work and live together.

The policy initiatives demonstrated an optimistic view of the information society but also signalled the danger of a two-tier society of have and have-nots.[20]

The EU policymakers foresaw a leading role for the market that should provide adequate funds for investments in infrastructure. The public sector had to provide the private sector with the correct regulatory framework and foster competition with policies like the pursuit of unitary open standards and a minimum regulatory standards. Liberalization of the telecom sector was considered essential and already well under way. The Bangemann report did not contain any detailed policies targeted at citizens. Main mission for the governments was to prepare citizens to accept these sweeping changes.[21]

In the 1990s, the regulatory mode brought a wide range of results. This included Directives[22] on IPR (software[23], data bases[24], satellite[25], rental & lending[26]), medical devices[27], unfair contract terms[28], data protection[29] and technical standards[30]. And of course the aforementioned Distance Selling Directive which was not intended for Internet sales but nevertheless turned out to be very important in the early years of e-commerce. In 2011 the Directive was repealed by the Consumer' Rights Directive[31].

[20] Marcut (2017), p. 35
[21] Marcut (2017), p. 36 ff.
[22] See the Annex for full references for directives and regulations published as of 1990.
[23] Directive 91/250/EEC
[24] Directive 96/9/EC
[25] Directive 93/83/EC
[26] Directive 92/100/EEC (currently no longer in force)
[27] Directive 93/42/EEC (currently no longer in force)
[28] Directive 93/13/EC
[29] Directive 95/46/EC currently no longer in force)
[30] Directive 98/34/EC
[31] Directive 2011/83/EC

The 2000s

Let us turn to the next decade. In 1999, the European Commission launched its eEurope initiative[32] in order to bring all relevant policy sectors under a coherent strategy. A strategy whose aim was to bring Europe fully into the information age; to a society where new technologies are embraced not only for a dynamic and innovative economy but for bringing benefits to all.[33]

Next the Lisbon Agenda for 2010 was set by the Council. The leading goal was formulated as: 'To become the most competitive and dynamic knowledge-based economy in the world'.[34] I still remember the first time I heard this formulation used by the Council. My reaction was that politicians now had lost touch with reality. This objective was not realistic and was also not achieved.[35]

The Lisbon agenda referred to 'an information society for all', with as main objectives:

1. to digitize citizens, private and public sector;
2. to help develop digital skills across Europe;
3. to build inclusiveness in the European Information Society (EIS).

In 2005 this was further detailed in the i2010 program.[36]

During this decade the regulatory mode brought a massive amount of new legislation, including seven telecoms related directives (incl. universal service, roaming and governance) and over 25 (mainly) information society directives, including on e-commerce, copyright, domain names, e-privacy, services (digital, financial, audio-visual media), consumer protection and e-money.[37]

[32] European Union (1999)
[33] Marcut (2017), p. 42 ff.
[34] https://www.europarl.europa.eu/summits/lis1_en.htm
[35] See Södersten (2019) for a broader analysis.
[36] European Union (2005)
[37] See references in the Annex.

The 2010s

In 2010, the European Commission launched a new initiative: the Digital Agenda for Europe.[38] Main objective was 'to maximise the social and economic potential of ICT'.

The flagship building block of the Agenda was the Digital Single Market.[39] This is a digital space corresponding to the EU Single Market, where online goods and services and, especially, information and knowledge, travel freely from one Member State to the other.

The regulatory mode in this decade delivered an impressive number of over 30 regulations and directives[40], including in the fields of public sector information/ open data, electronic identification and trust (eIDAS regulation), exchange of information regarding technical regulations, payment services, data protection (incl. the GDPR and a proposal for an e-privacy regulation), cybersecurity and consumer protection.

The 2012 EU Regulation on European standardisation[41] was a landmark for European standard setting. As a key element the Regulation provided for a legal framework allowing the Commission to request European Standardisation Organisations to draft standards for regulatory purposes. Furthermore it provided EU support to the functioning of the European Standardisation System and sets outs key criteria for the functioning of that system. Also it opened the backdoor a little bit for government's use of technical specifications not originating from European standardisation. This by allowing Member States to use (under restrictive conditions) standards set by industry outside the scope of recognized bodies (so-called fora or consortia standards) for public procurement purposes.

[38] European Union (2010)
[39] See for the Digital Single Market and a comparison with the Single Market: Marcut (2017), p. 75 ff.
[40] See the Annex for a complete overview and references.
[41] Regulation 1025/2012 (European Union (2012))

The 2020s

In 2020, the second five-year digital strategy 'Shaping Europe's digital future'[42] was published by the Commission. The strategy focused on three key objectives: technology that works for people, a fair and competitive economy and an open, democratic and sustainable society. In 2021 these objectives were put into more concrete terms in the '2030 Digital Compass: the European way for the Digital Decade'[43] which evolves around four cardinal points: 1. digital skills, 2. digital transformation of businesses, 3. secure and sustainable digital infrastructures and 4. digitalisation of public services.

Related technological priorities include: quantum computing, blockchain, artificial intelligence ('human centric'), digital sovereignty cybersecurity, chips, European data spaces and setting global technology standards.

In the current decade important regulatory achievements so far include proposals in the fields of artificial intelligence, cyber resilience (incl. NIS2 and later this year an initiative on EU cyber resilience) and proposals for a Digital Markets Act, a Digital Services Act, a Data Act, a Data Governance Act and a European Health Data Space.[44] Also, early this year a proposal for amendment to the European Standardisation Regulation was published.[45] This draft focusses on desired changes in the representation in the standardisation process and has ignited a fierce debate between the European standardisation bodies, in particular ETSI, and the European Commission.

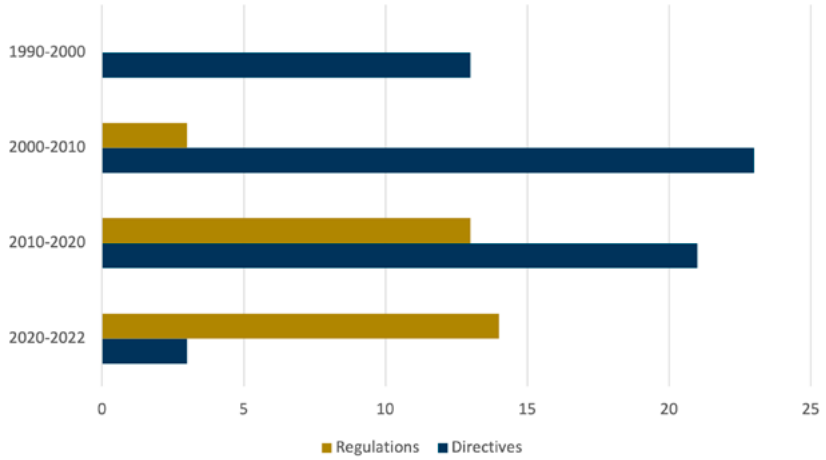
[42] https://ec.europa.eu/info/sites/default/files/communication-shaping-europes-digital-future-feb2020_en_4.pdf
[43] European Union (2021)
[44] See the Annex for references
[45] COM(2022) 32 final

Table 2 - EU Policy agenda & regulatory mode (overview)

1990s	DELORS WHITE PAPER/ BANGEMANN REPORT ('Europe and the Global Information Society')	Telecoms, Privacy, IPR, Medical devices, Unfair contract terms, Technical standards, Consumer Protection
2000s	eEurope Action Plan/ LISBON AGENDA FOR 2010/ i2010	Telecoms, Copyright, Domain names, e-Privacy, Financial services, Services, Consumer protection, e-Money, Audio-visual media services
2010s	DIGITAL AGENDA FOR EUROPE: 2010-2020 - Shaping Europe's digital future - Europe's Digital Decade	Public sector information / Open data, Electronic ID and trust, Technical regulations, Financial services, Data protection, Standardisation, Consumer Protection
2020s	DIGITAL AGENDA FOR EUROPE: 2020-2030 - Digital Compass	(Proposals for) AI, Cyber resilience, Telecoms, Digital Markets, Digital Services, Data and Data Governance, Chips, Health Data Spaces

In numbers, the digital regulatory 'production' of the EU over the last decades looks as follows.

Table 3 – Directives vs Regulations (1990 -)



Looking at these numbers, let me make a few comments.

1. In the last 20 to 25 years we have seen the rise of a tsunami of regulatory initiatives for the European digital society with currently already nearly ninety dedicated directives and regulations[46] being drafted and the vast majority (over 80%) thereof already in effect.

2. Over time a significant number of (especially) directives (nearly twenty) has been replaced. This due to a variety of reasons, including:

   A. replacement by a regulation to ensure (further) harmonisation (e.g. medical devices, data protection, electronic signatures); and/or

   B. replaced by an instrument with an advanced approach and/or widened scope to the relevant topic (e.g. provision of information in the field of technical standards and regulations but as well again data protection, medical devices and electronic signatures); and/or

   C. consolidation (e.g. certain aspects of telecommunications legislation).

[46] See the introduction of the Annex for a description of the scope and the underlying choices made in coming to the aforementioned number of directives and regulations.

3. Over the last two years an impressive number of 15 proposals for (mainly) regulations on key topics like access to data, data governance, artificial intelligence, digital services, platforms and chip production have been launched.

4. The body of EU legislation referred to above is to some extent merely the tip of the iceberg. This not only because I have restricted myself to directives and regulations, leaving a wide range of other legislative acts as well as relevant case law, policy documents etc. out of scope. Also, due to the intrusion of ICT in all sectors of our society, a very wide range of legislation has become relevant when looking at the way the digital society is being regulated. Prominent legislative examples include labour law and administrative law. For instance, the management of Zap, a flash delivery service, recently announced it was dismantling its business operations in the Netherlands due to a dark store ban and ongoing regulatory uncertainty. Furthermore, over time a wide range of traditional legislation has been 'infused' with digital elements.

5. As regards the choice of European regulatory instruments we initially see an overwhelming amount of directives, which left of course room for national deviations. Over time, the EU increasingly turned to regulations (such as the GDPR) to further harmonize rules and eliminate member-state disparities. Over the last few years regulations constitute the vast majority of legislative proposals.

6. Another potential trend seems to be a movement towards stricter enforcement or at least higher penalties (including a certain percentage of the entire global turnover in the preceding fiscal year)[47]. Also we see more recent attempts to move away from a central enforcement role for national supervisory authorities. This no doubt fuelled by the negative experiences with the GDPR in this respect.[48]

7. Under pressure of big data and artificial intelligence we have seen a growing fundamental rights focus in the last decade.[49]

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47 E.g. in the GDPR.
48 Heine (2021)
49 See amongst others Gerards et al (2020) and Kosta et al (2022).

Obviously much more is to be said about what happened in the last 25 years but that would bring me far beyond the scope of this lecture.

Let me conclude this chapter by one observation regarding the research focus in the last decades. When it comes down to regulatory approaches, it occurs to me that the overwhelming majority of research efforts has focussed on either (constructing) regulatory theories, domain approaches to regulation (e.g. in fields like data protection, cybersecurity or artificial intelligence) or individual pieces of regulation (like the GDPR or the draft EU Act on Artificial Intelligence). To my knowledge far less attention has been given to the 'architecture' and interdependencies in the digital regulatory structure that has emerged in the EU over the last decades.[50] I realise that this observation may be driven by my own research focus and scope of work.[51] If my observation is correct, then interesting research questions lie ahead.

[50] Some overarching aspects have however been highlighted, like the so-called 'Brussels effect' of the EU regulatory approach. See: Bradford (2020). Another example could be the fundamental rights focus as mentioned above. Nevertheless there seems to remain fertile ground for further research.

[51] I apologize on forehand to those authors whose work or focus on the aforementioned overarching aspects I have either misinterpreted or overlooked in preparing this lecture.

3 The proposal for a European Health Data Space

As part of its European strategy for data, the Union aims at creating a single market for data to ensure Europe's global competitiveness and data sovereignty.[52] Common European 'data spaces' will be created to ensure that more data becomes available for use in the economy and society, while keeping those who generate the data in control.

In that context, the European Union introduced a Proposal for a Regulation on the European Health Data Space (EHDS)[53] early May 2022. There a four reasons why this proposal is particularly interesting in the context of this lecture:

1. the proposal resembles a miniature world of regulatory challenges relevant for the digital society as a whole;

2. the EU actually has so far very few competences in the field of health care[54];

3. the proposal leads to questions about the way technical standard are being approached;

4. the proposal is at odds with the much stricter approach the Dutch government has chosen to ensure interoperability in the field of health information exchange.

The EU has identified a lack of 'access' as the main driver for this initiative. This concerns both data access for patients, healthcare professionals and research and market access for industry.[55]

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[52] See: https://digital-strategy.ec.europa.eu/en/policies/strategy-data

[53] COM(2022) 197 final

[54] Under Article 168(7) of the Treaty on the Functioning of the European Union, Member States are responsible for the definition of their health policy and for the organisation and delivery of health services and medical care. The role of the EU is formally limited to complementing national policies and supporting cooperation between member countries in the field of public health. Major pillars of the EU approach and numerous actions plans, research programs, stimulating standard and reference models, as well as other non-binding initiatives. Nevertheless there is still a wide range of binding EU legislation relevant for healthcare delivery in the Member States. Next to the EU Directive 2011/24 on the application of patients' rights in cross-border healthcare ([2011] OJ L 88/44) this includes legislation in the fields of data protection, electronic identification services, digital services, cyber security, product safety and market structure legislation. See for further details: Stuurman (2021).

[55] COM (2022) 197 final, p. 1 ff.

Core of the EHDS proposal is constituted by the following three elements:[56]

1. The *primary use of health data,* including:
   A. to support data being shared between healthcare providers, mandatory requirements for interoperability, security, safety and privacy;
   B. mandatory self-assessment of electronic health record systems covering interoperability and security;
   C. all Member States will be required to participate in a cross-border digital infrastructure for the exchange of data for healthcare delivery: (MyHealth@EU).

2. The *secundary use of health data,* including:
   A. the creation of another new and decentralised EU infrastructure for health data (HealthData@EU) that will connect health data access bodies across all Member States;
   B. Participation in this EU-infrastructure is mandatory for all Member States; this will facilitate cross-border studies.

3. A *new governance mechanism* consisting of a new European Health Data Space Board composed of the representatives of digital health authorities and new health data access bodies, the Commission and observers. In each Member State one or more designated health data access bodies will be established that can provide access to electronic health data to third parties, building on the Data Governance Act.

The EHDS proposal is connected to a range of other (proposed) regulations. Alignment with the GDPR is obvious of key importance given the sensitive nature of health data. In the EHDS proposal the EU intends to establish the legal basis for access to, and use of, health data under the GDPR. Recently the European Data Protection Board and the European Data Protection Supervisor, although acknowledging the Commission's efforts to align the Proposal with the GDPR provisions, issued critical comments and stressed 'the need to clarify the relationship between the provisions in this Proposal, the ones in the GDPR and Member State law and also with ongoing European initiatives'.[57]

[56] See COM (2022) 197 final and European Union (2022a).
[57] EDPB-EDPS Joint Opinion 03/2022

Next to the GDPR, the EHDS further also builds upon the proposed Data Governance Act[58] and the proposed Data Act[59] as well as on the new proposal on European Digital Identity[60]. Also it links with cybersecurity legislation in the form of the NIS Directive[61] (and its forthcoming replacement NIS-2[62]) as well as with the proposal for a Cyber Resilience Act[63] planned for publication later this year.

Another key element of the EHDS proposal are the requirements for so called electronic health record systems ('EHR systems'). The EHDS sets essential requirements specifically for EHR systems in order to promote interoperability and data portability. In the next chapter I will return to this and other aspects of the EHDS as a case study for the way standards are being (or rather could have been) used by the European regulator.

[58] COM(2020) 767
[59] COM(2022) 68
[60] COM(2021) 281
[61] Directive 2016/1148/EU
[62] COM(2020) 823
[63] See: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13410-Cyber-resilience-act-new-cybersecurity-rules-for-digital-products-and-ancillary-services_en

4 The role of technical standards in the EU digital regulatory framework

Let us now turn to standards and standardisation as a second governance mode under the EU digital policy approach. To start with, an important question is: what is actually 'a technical standard'? There are many definitions of a standard but one of the fascinating aspects of this topic is that there's actually, to some extent, a lack of standardisation when it comes down to defining the content of this term.[64]

In the legal domain, EU Regulation 1025/2012[65] provides for a definition of a standard building on four key elements:

1. a technical specification;

2. adopted by a recognised standardisation body;

3. repeated or continuous application; and,

4. voluntary.

Under the Regulation, a standard can be any one of the following[66]:

1. an 'international standard' (means a standards adopted by an international standardisation body (e.g. ISO));

2. a 'European standard' (means a standard adopted by one of the three European standardisation bodies (ETSI, CEN or CENELEC));

3. a 'harmonised standard' (a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation); or,

4. a 'national standard' (a standard adopted by a national standardisation body, like NEN).

64 See De Vries (1997) on the classification of standards.
65 European Union (2012), Art. 2
66 Art. 2

Technical standards are kind of hard to catch. Some standards relate to a physical form and, at least when implemented, the result thereof can be seen. Most standards cannot be observed in that way (other than a representation on paper or on a computer screen). Did you for instance know that there are hundreds of standards implemented in a laptop? The total number might even be 500 or more. Technical standards are however omnipresent and something like the oxygen for modern life. Oxygen can also not be seen but you'll notice immediately when it is not available or not in adequate quality or quantity.

This not only holds for the technical world but it has much broader scope. Standards do no longer only refer to nuts and bolts but cover a broad range of topics including corporate social responsibility, data protection, ethics etc. etc.[67] As Busch[68] argues, standards shape *'the physical world around us but also our social lives and even our very selves'*.

How to illustrate that that you won't see a standard unless it fails or there are competing standards? I looked for inspiration in my own living room. I guess the outcome is familiar to all of you. Everybody has a drawer or box with a spaghetti-like twisted load of cables and plugs used for charging or connecting old and new electronical equipment. These drawers or boxes are interesting because the contents thereof seems to be one of the more tangible and widespread 'gifts' of the digital society to all its participants. Obviously the content thereof is very interesting from an historical perspective as well. It will determine what your real 'digital age' is as well as the depth and breadth of your experience. Should one, for instance, find traces of ISDN connections, faxes or even floppy disks, then you are probably from the 'digital stone age' or before like me. As you will have read in the newspaper recently[69], the EU will impose USB-c as the standard charging cable for numerous electronic devices. That should free up space in your home as well!

[67] See: Busch (2011), Kamara (2021) and European Union (2021a).
[68] Busch (2011), p. 2
[69] See as well the EU Parliament press release of 7 June 2022 at: https://www.europarl.europa.eu/news/nl/press-room/20220603IPR32196/deal-on-common-charger-reducing-hassle-for-consumers-and-curbing-e-waste

Standardisation is of strategic importance. The famous slogan 'who has the standard, has the market' expresses it all.[70] When standards are so important, then from a European perspective the question arises whether the body of European standards and the European standardisation system is in shape to meet current and future economic and technological challenges? Unfortunately there are ongoing concerns, both at the side of the European standardisation organisations as on the side of the EU. Earlier this year, the European Commission was also unusually sharp in its Standardisation Communication.[71] A worrying situation looking at the strategic issues at stake.

Now let's turn to the regulatory application of technical standards.

As far as *reference to standards* (the most common technique) is concerned four levels can be observed.

1. *Reference to standards as a possible regulatory instrument.*
   An example is provided by the E-commerce Directive[72], Consideration 41: 'This Directive strikes a balance between the different interests at stake and establishes principles upon which industry agreements and standards can be based.'

2. *Encourage the voluntary use of standards.*
   An example is provided by article 42 GDPR under which 'the establishment of data protection certification mechanisms and of data protection seals and marks, for the purpose of demonstrating compliance with this Regulation' is encouraged. However no given legal significance is attached to conformity with the standards underlying a certificate.

3. *Standards positioned as a relevant element in (a) establishing conformity/ compliance or (b) compliance with standards gives a presumption of conformity.*
   Examples of the latter, inspired by or complying with the so-called 'New Approach' (see below), in the digital arena can be found in the draft AI

[70] From a regulatory point of view, trade laws play an important role in steering the effects of the application of standards in international economic relations. See: Delimatsis (2019).
[71] European Union (2022)
[72] Directive 2000/31/EC

Act[73] (Art. 40; high risk systems) and the draft Data Act[74] (Article 28; interoperability presumption of conformity for operators of data spaces).

4. *Mandatory application of a standard (harmonised standard, international or European standards or other technical specifications).*
   A rare example is the Radio Equipment Directive proposal[75] for mandatory use of USB-C as the common charging port for all mobile phones, tablets and cameras in the EU, by autumn 2024. Another example can be found in the GDPR relating to the mandatory application of an ISO standard for accreditation by the relevant national accreditation body.[76]

The approach referred to above under 3 sub b. in which compliance with standards results in a presumption of conformity, is referred to as the 'New Approach'.[77] This regulatory technique has especially been developed for European product legislation en route to realisation of the internal market in 1992.[78]

Under this New Approach the relevant EU Directives, e.g. for Toy Safety[79], merely define the 'essential requirements' for a product (such as the required level of safety). The technical specifications conforming to the essential requirements are laid down in 'harmonised European standards' (drafted by one of the three European standardisation organisations upon the request of the European Commission). When the references to these standards have been formally published by the European Commission, conformity with these standards implies that a producer of a product is presumed to be in conformity with the requirements of the relevant Directive. This is expressed by mandatory affixing of the 'CE' mark (meaning: Conformité Européenne), which you will find e.g. on your phone, constituting a European passport for these products to freely travel

73 COM(2021) 206 final
74 COM(2022) 68 final
75 COM (2021) 547 final
76 Art. 43 par. 1 sub b GDPR
77 European Union (1985). See amongst others Pelkmans (1986).
78 The 'New Approach' is a co-regulatory approach deploying private technical standards within a public law regulatory framework in order to facilitate product market access and safety. This approach has been developed in the EU in the 1980s in order to accelerate the elimination of technical barriers to trade and the removal of uncertainty for economic operators, with the view of achieving a Single European Market by 1992. (European Union (1985)
79 European Union (2009)

within the European Economic Area.[80] This New Approach concept is primarily applied in the field of product legislation; an equivalent for services was never developed.[81]

In sum it can be concluded that insofar as technical standards are referred to in digital regulations, the most common purpose thereof appears to be encouraging the use of standards as a purely voluntary tool. We do see however application of the New Approach, or parts thereof, in some recent proposals for digital regulations (the proposed AI Act[82] and the proposed Data Act[83] as well as in the aforementioned proposal for a European Health Data Space[84] regulation). In the latter, a presumption of conformity is obtained for EHR systems on the basis of compliance with technical specifications and mandatory affixing of CE marking. A striking difference with the New Approach is however the fact that elaboration of the essential requirements will in this proposal not take place in the form of European standards but by means of 'common specifications' to be adopted by the Commission.[85] Hence no harmonised European standards as the basis for issuing a presumption of conformity. Furthermore it is remarkable that under the EHDS proposal conformity will be established by means 'self-assessment' by the suppliers of EHR systems instead of via third party certification. The proposal actually refers to 'mandatory self-certification'[86]. This phrase seems incorrect. Certification is inherently considered a third party process[87];'self-assessment' seems a more appropriate phrase.[88]

An intriguing question is obviously why the Commission seems to by-pass the European standardisation system and would merely rely on self-assessment for something critical as ensuring interoperability? References in the proposal to administrative burdens, costs and 'potential capacity limitations of notified bodies

[80] European Union (2016)
[81] Van Leeuwen (2017)
[82] COM(2021) 206 final
[83] COM(2022) 68 final
[84] COM (2022) 197 final
[85] Consideration 33
[86] COM (2022) 197 final, p. 14
[87] This in conformity with the ISO definition: 'Certification – the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements'. (https://www.iso.org/certification.html)
[88] See on the terminology issue also: Lachaud (2019), p. 43 ff.

for third-party certification' give the impression of strong industry pressure against third party involvement.

Given the critical nature of interoperability in the exchange of health information, the Dutch government in 2020 proposed legislation (EGIZ: electronic data exchange in healthcare)[89] based on a very strict governance mechanism:

1. mandatory application of standards (currently being developed by the NEN, the Royal Netherlands Standardisation Institute); and,

2. mandatory certification by state approved certification bodies.

The exact impact of the introduction of the recent EU proposal for a European Health Data Space on the Dutch legislative initiative remains to be seen. For now, the Dutch Minister for Healthcare has decided to continue the development of Dutch standards. Potentially they could be part of the specifications that in the future to be set by the European Commission under the EHDS proposal.[90]

Standardisation raises all kinds of interesting legal and regulatory questions. Earlier today in a seminar we discussed a series of interesting questions under the title 'Standardisation: Access, Expertise and Good Governance'.[91] Many of these questions relate to the way the interface between the public and the private sector works or should work. A problem not unique for standardisation but nevertheless persistent and challenging to solve. This also in view of changing power structures.

Obviously the legal status of technical standards is a prominent question in that context as well. In the 2016 James Elliott Construction case[92], the Court of Justice of the European Union ruled that 'a harmonised standard such as that at issue in the main proceedings, adopted on the basis of Directive 89/106 and the

[89] EGIZ Bill (2020)
[90] Letter to the House of Representatives of 19 May 2022, TK 27529, nr. 277 (
[91] For program and research questions see: https://www.tilburguniversity.edu/current/events/tilt-seminar-290622. I want to express my sincere gratitude to my colleagues Panos Delimatsis, Shanya Ruhela, Irene Kamara and Maartje van Genk for organising this seminar on the occasion of my farewell. I am also grateful for the financial support provided by NEN and the Tilburg Law School.
[92] Case C-613/14 James Elliot Construction Limited v. Irish Asphalt Limited, EU: C: 2016: 821.

references to which have been published in the Official Journal of the European Union, forms part of EU law.'[93] This case law triggered an extensive debate that continues until today.[94] Although also relevant in the context of regulatory use of standards[95] I will - given the focus of the preceding seminar - refrain from discussing this and related issues in the context of my speech any further.

Standards are potentially a very useful regulatory tool but their use also requires maintenance and improvement.[96]

In 2015 the predecessor to the current Dutch Advisory Board on Regulatory Burden[97] published an interesting report[98] in which it concluded that the use of standards in Dutch legislation does not come without concerns. Main issues include:

1. unclear references;

2. unnecessarily high costs for alternative solutions;

3. great complexity of standards, as a result of which the legally required standards often do not match the practice of citizens and small businesses.

The report did to my knowledge not receive much attention when it was published. I was however happy to learn recently that at least the issue of accessibility of standards still receives attention. In a recent motion by the Dutch House of Representatives, the government is requested to make efforts to further improve the accessibility of NEN standardisation committees for small SMEs and to consider the possibilities for financial support for participation in developing standards. The Minister's response[99] states that also aspects such as language use in standards are receiving attention within NEN.

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93 Case C-613/14, par. 40

94 In amongst others Eliantonio & Cauffman (2020) a number of the relevant dimensions are being discussed. On the legal qualification of standards see Kamara (2021) and the literature referenced therein.

95 This includes issues like the access to standards (free of charge when 'part of EU law')?

96 This obviously next to quality aspects like legitimacy, consistency, accessibility etc.

97 https://www.atr-regeldruk.nl/

98 ACTAL (2015)

99 Letter to the House of Representatives of 28 April 2022, TK 27.879, nr. 88 (Versterking van de positie van de consument)

To conclude this part: standards are being applied in regulations in various ways. In most cases, standards referred to by the legislator constitute a purely voluntary instrument, and – something we could not discuss today – are the basis for diverging ways of conformity assessment. This lack of a harmonised approach creates an additional burden for industry and leaves the potential of standardisation partly underused.

For the near future, standard setting is facing severe challenges. These do not only concern the strategic role of European standards on the global level[100] but include as well the availability of expertise (Europe needs new generations of standardisers) and the way in which better use can be made of the existing body of standards.

It is my strong believe that research and education are key instruments in facing these challenges. Many colleagues in the audience today are involved in research and education in the field and I hope that governments and other sources for funding will more than currently recognize the strategic value of their work.

With the SOONS foundation[101], NEN set a good example for fostering the cooperation with academia in the field of standardisation research and education.

[100] As addressed in European Commission (2022).
[101] https://www.stichting-soons.nl/

5 Concluding remarks

Looking back twenty years, we can see that an impressive structure of European digital regulations has emerged.

It is enough to face the current and future societal challenges of digital technologies? That question automatically leads to the next one: what is actually the standard to determine what is adequate? If we take the goals as set out in European digital policy agenda as a yardstick, we see that the European ambitions have been tightened up over the last decades. Now, the goals for the current digital agenda are more ambitious and challenging than ever, with recently a 'blockbuster' topic as 'digital sovereignty' (whatever it might exactly mean...)[102] added. But we also see that the interpretation of existing goals is shifting. For example, creating a safe digital environment nowadays calls for much more than say twenty years ago.

Both the policy ambitions as well as technology and societal and political views and power relations, are constantly changing. There is hence no fixed point against which we can measure progress or quality but it is rather a journey in an ever changing landscape. That journey is progressing but new threats and opportunities are emerging just as quickly.

Overall, I believe that we should prepare for much further reaching regulatory interventions if we really want to safeguard the core values of our society in the digital domain. If we look for instance to the field of data protection, the GDPR is in my view merely a beginning. Far more radical interventions seem inevitable if we want to really reclaim our privacy in digital space. That will also require different business models. There needs to be more choice and we must collectively get rid of our addiction to 'free' services'. I cannot yet oversee right now whether the proposed Data Act and Data Governance Act will be enough to reclaim control over data in the broader sense but I am not sure about that in advance.

In hindsight it looks like we have had the luxury to start building a European information society in relatively peaceful and politically stable times. Many of the starting points that seemed 'given' for so long are however under pressure now.

In sum: overall, we have dealt with major challenges in building the digital society and its rule book but maybe much more is yet to come. Great challenges lie ahead at the intersection of law, technology and society. With ongoing

[102] Compare: Van Dijck (2022)

technological emersion of our society, technical standards will even become more relevant than they are today. As concluded above the potential of standardisation as a regulatory tool is still partly underused. European standardisation is facing strategical challenges that will have to be resolved on the short term to safeguard European interests on the global level.

With some many interesting developments going on in the field it is not easy to say goodbye to academic work and especially my TILT colleagues. I am convinced that they will continue to play an important role in the ongoing debate. Personally, I will continue to follow the developments be it from a distance and amidst new perspectives.

Dan spreek ik nu nog graag een dankwoord uit.

6 Dankwoord

- Beste Corien, het zal ergens rond 1999 zijn geweest dat jij mij belde met de vraag om eens te overleggen over een mogelijke rol in Tilburg. Wij spraken af bij jou thuis en wisselden wat ideeën uit. Dat leidde later tot een benoemingsprocedure en in 2001 startte ik mijn werkzaamheden bij het CRBI. Ik kijk met genoegen terug op ook die beginperiode en dank je voor onze contacten door de jaren heen en de mogelijkheden die je mij hebt geboden in Tilburg.

- Beste Ronald, ik kijk met veel genoegen terug op onze contacten. Fijn ook om geregeld met jou even te kunnen bijpraten over wat er speelde in de vakgroep; dat heeft mij mede het gevoel gegeven er bij te horen hoewel ik er natuurlijk lang niet altijd bij kon zijn.

- Beste Colette, onderwijs was een van mijn speerpunten en dat betekende dan geregeld contact met jou in je rol van onderwijsdirecteur en als mede-docent bij TIAS. Wat was het leuk met jou samen te werken. Dank je; ik ga onze contacten missen.

- Beste Maurice, wij hebben samen aan een paar uitdagende PhD-trajecten gewerkt. Veel dank voor jouw deskundigheid en inzet daarbij en ook voor je jarenlange bijdragen aan Contracts & ICT. Je werkt altijd weer aan mooie onderwerpen waarbij je een grote kennis en kwaliteit laat zien. Wat mooi.

- Dear Irene, there are not many lawyers with interest and hands on experience in standardisation and I was very happy to have you around during the last few years. I am proud that you continue working in Tilburg and see a bright future ahead for you.

- Dear Eric, thank you for our cooperation over the last years. I really valued working with you.

- Dear TILT colleagues, thank you for providing a setting in which we could discuss so many interesting themes. It was my pleasure working with you in research and education.

- Lieve kinderen, toen ik werd benoemd in Tilburg waren jullie nog te jong om te beseffen wat een hoogleraar doet. Nu hebben jullie daar meer zicht op maar gaat de toga uit en geen dinsdagen meer naar Tilburg. Heel leuk dat Demi en Suus erbij zijn; hebben jullie opa toch nog een keer in toga gezien.

- Lieve Irene, met het verdedigen van mijn proefschrift waren mijn wetenschappelijke ambities nog niet vervuld. Jij reageerde gelukkig heel positief toen een hoogleraarschap in Tilburg in beeld kwam. Dat betekende natuurlijk lange dinsdagen in Tilburg en dus laat thuis. De andere werkdagen op kantoor waren als regel niet korter en ook in het weekend was er altijd weer werk te doen. Veel kwam dan ook op jouw schouders terecht. Veel dank dat je dat allemaal hebt opgebracht. Door corona was ik de laatste jaren al veel thuis maar natuurlijk ook weer veel aan het werk. Nu wordt het eindelijk rustiger en wordt het vooral 'samen leuke dingen doen'. Wat een mooi vooruitzicht!

Ik heb gezegd

7 Literature

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8 Annex

This Annex contains an overview of nearly ninety (proposed) directives and regulations that have been drafted over the last three decades aimed at fostering the digital society. The vast majority thereof (well over 80%) has already taken effect.

For various reasons this overview is however not fully complete.

The criterium 'aimed at fostering the digital society' is highly subjective. Digitisation plays a role somewhere in the chain in almost all social sectors and activities. Where is the line drawn? I have in general opted for a relatively strict selection criterion: an immediately recognisable focus on 'digital'. This is to be distinguished from 'relevance for the digital society' since that criterium applies to a vast array of legislation since large parts of social and economic activity are taking place online nowadays. As a consequence for example a number of IPR related directives and regulations (e.g. on trade secrets and trade marks) have not been included in the overview although they are highly relevant in the digital society.

Some (proposed) directives and regulations included in the overview nevertheless have a wider scope/more general focus but are either key for the functioning of the digital society (like consumer contracting) or crucial for digital applications in a given sector (like medical devices) and have hence been included in this overview. I realize that these choices are somewhat arbitrary; there is my view no clear cut 'digital' carve out. I have tried to include EU legislation concerning telecommunications and media as much as possible but a disclaimer applies.

The overview is limited to (proposed) directives and regulations. This means that a wide range of other legislative acts, as well as relevant case law, policy documents etc. remain out of scope. This solely on practical grounds; a (more) complete overview would have required a lot of extra research time and resembled a PhD trajectory more than (at least my appreciation of) preparing a farewell speech.

A number of directives and regulations has been replaced or amended over time. Nevertheless they have been included in the overview given the important role of especially the legislation crafted in the early years development of the digital society (and sometimes far beyond that). Examples include Directive 97/7 in the field of e-commerce and Directive 95/46 on data protection.

Nr.	YEAR	TITLE
1.	1991	[Software Directive (original version)] Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs [1991] OJ L122/42
2.	1993	[Medical Device Directive] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L169/1 (currently no longer in force)
3.	1993	[Satellite and Cable Broadcasting Directive] Council Directive 93/83/EEC of 27 September 1993 on the coordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission [1993] OJ L248/15
4.	1993	[Unfair Terms in Consumer Contracts Directive] Directive 93/13/EC of 5 April 1993 on unfair terms in consumer contracts [1993] OJ L95/29
5.	1995	Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31 (currently no longer in force)
6.	1996	[Database Directive] Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases [1996] OJ L 77/20

7.	1997	[Distance Selling Directive] Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts [1997] OJ L144/19 (currently no longer in force)
8.	1997	[Telecommunications Privacy Directive (ISDN Directive)] Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector [1997] OJ L24/1 (currently no longer in force)
9.	1998	[Technical Standards Directive] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and on rules on information society services [1998] OJ L204/37 (currently no longer in force)
10.	1998	Directive 98/48/EC of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations [1998] OJ L217/18 (currently no longer in force)
11.	1999	[Sales and Guarantees Directive] Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees [1999] OJ L171/12 (currently no longer in force)
12.	1999	[E-Signatures Directive] Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures [2000] OJ L13/12 (currently no longer in force)

13.	2000	[Electronic Commerce Directive] Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market [2000] OJ L178/1
14.	2001	[Copyright Directive (InfoSoc Directive)] Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society [2001] OJ L167/10
15.	2002	[Universal Service Directive] Directive 2002/22/EC of the European Parliament and of the Council of 7 March 2002 on universal service and users' rights relating to electronic communications networks and services [2002] OJ L108/51 (currently no longer in force)
16.	2002	[Access Directive] Directive 2002/19/EC of 7 March 2002 of the European Parliament and of the Council on access to, and interconnection of, electronic communications networks and associated facilities [2002] OJ L108/7 (currently no longer in force)
17.	2002	[Framework Directive] Directive 2002/21/EC of 7 March 2002 on a common regulatory framework for electronic communications networks and services [2002] OJ L108/33 (currently no longer in force)
18.	2002	[Authorisation Directive] Directive 2002/20/EC of 7 March 2002 on the authorisation of electronic communications networks and services OJ L108/21 (currently no longer in force)
19.	2002	[.eu Domain Name Regulation] Regulation (EC) 733/2002 of the European Parliament and of the Council of 22 April 2002 on the implementation of the.eu Top Level Domain [2002] OJ L113/1

20.	2002	[E-Privacy Directive] Directive on Privacy and Electronic Communications) Directive 2002/58/EC of 12 July 2002 of the European Parliament and of the Council concerning the processing of personal data and the protection of privacy in the electronic communications sector [2002] OJ L201/37
21.	2002	[Distance Marketing of Consumer Financial Services Directive] Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services, amending Directives 97/7/EC and 98/27/EC [2002] OJ L271/16
22.	2004	[Intellectual Property Rights Enforcement Directive (IPRE Directive)] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L195/16
23.	2005	[Unfair Commercial Practices Directive (UCP Directive)] Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directive 97/7/EC, Directive 98/27/EC and Directive 2002/65/EC of the European Parliament and of the Council and Regulation (EC) 2006/2004 of the European Parliament and of the Council [2005] OJ L149/22
24.	2006	[Rental and Lending Rights Directive (codified)] Directive 2006/115/EC of the European Parliament and of the Council of 12 December 2006 on rental right and lending right and on certain rights related to copyright in the field of intellectual property (codified version) [2006] OJ L376/28
25	2006	[Services Directive] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market [2006] OJ L376/36

26.	2006	[Data Retention Directive] Directive 2006/24/EC of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC [2006] OJ L105/54 (currently no longer in force)
27.	2006	[Misleading Advertising Directive] Directive 2006/114 of the European Parliament and of the Council of 12 December 2006 on misleading and comparative advertising [2006] OJ L376/21
28.	2007	Regulation (EC) 717/2007 of 27 June 2007 on roaming on public mobile telephone networks within the Community and amending Directive 2002/21/EC [2007] OJ L171/32 (currently no longer in force)
29.	2007	Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) [2007], OJ L 108/1
30.	2007	[Audio-visual media services without frontiers Directive] Directive 2007/65/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directive 89/552/EEC on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities [2007] OJ L 332/27 (currently no longer in force)
31.	2009	[Software Directive (codified)] Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (codified version) [2009] OJ L111/16

32.	2009	[Consumer Injunctions Directive] Directive 2009/22/EC of the European Parliament and of the Council of 23 April 2009 on injunctions for the protection of consumers' interests (codified version) [2009] OJ L110/30
33.	2009	Regulation (EC) 1211/2009 of 25 November 2009 establishing the Body of European Regulators for Electronic Communications (BEREC) and the Office, [2009] OJ L337/1 (currently no longer in force)
34.	2009	[Citizens' Rights Directive] Directive 2009/136/EC of 25 November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services, Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector and Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws [2009] OJ L337/11
35.	2009	[Better Law-Making Directive] Directive 2009/140/EC of 25 November 2009 amending Directives 2002/21/EC on a common regulatory framework for electronic communications networks and services, 2002/19/EC on access to, and interconnection of, electronic communications networks and associated facilities, and 2002/20/EC on the authorisation of electronic communications networks and services [2009] OJ L337/37

36.	2009	Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services, Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector and Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws [2009] OJ L 337/11
37.	2009	[E-Money Directive] Directive 2009/110/EC of the European Parliament and of the Council of 16 September 2009 on the taking up, pursuit and prudential supervision of the business of electronic money institutions, amending Directives 2005/60/EC and 2006/48/EC and repealing Directive 2000/46/EC [2009] OJ L267/7
38.	2009	Second Amending Directive (Telecoms) Directive 2009/140/EC of 25 November 2009 amending Directive 2002/21/EC on a common regulatory framework for electronic communications networks and services, Directive 2002/19/EC on access to, and interconnection of, electronic communications networks and associated facilities, and Directive 2002/20/EC on the authorization of electronic communications networks and services [2009] OJ L337/37
39.	2010	[Audio-visual Media Services Directive] (codified version) Directive 2010/13/EU, of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audio-visual media services [2010] OJ L95/1

40.	2011	[Consumer Rights Directive (CRD Directive)] Directive 2011/83/EC of 25 October 2011 of the European Parliament and of the Council on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council [2011] OJ L304/64
41.	2011	[Copyright Term Directive] Directive 2011/77/EU of the European Parliament and of the Council of 27 September 2011 amending Directive 2006/116/EC on the term of protection of copyright and certain related rights [2011] OJ L265/1
42.	2011	[Child Pornography Directive] Directive 2011/93/EU of the European Parliament and of the Council of 13 December 2011 on combating the sexual abuse and sexual exploitation of children and child pornography, and replacing Council Framework Decision 2004/68/JHA [2011] OJ L26/1
43.	2012	Regulation (EU) 531/2012 of 13 June 2012 on roaming on public mobile communications networks within the Union, [2012] OJ L172/10 (currently no longer in force)
44.	2012	[Orphan Works Directive] Directive 2012/28/EU of the European Parliament and of the Council of 25 October 2012 on certain permitted uses of orphan works [2012] OJ L299/5
45.	2013	[Alternative Dispute Resolution Directive (ADR Directive)] Directive 2013/11/EU of the European Parliament and of the Council of 21 May 2013 on alternative dispute resolution for consumer disputes and amending Regulation (EC) 2006/2004 and Directive 2009/22/EC [2013] OJ L165/63

46.	2013	[Online Dispute Resolution Regulation] Regulation (EU) 524/2013 of the European Parliament and of the Council of 21 May 2013 on online dispute resolution for consumer disputes and amending Regulation (EC) 2006/2004 and Directive 2009/22/EC [2013] OJ L165/1
47.	2013	Directive 2013/37/EU of the European Parliament and of the Council on the Re-use of Public Sector Information "Unblocking the Economic Potential of Public Data" [2013] OJ L 175/1 (currently no longer in force)
48.	2013	[Attacks Against Information Systems Directive] Directive 2013/40/EU of the European Parliament and of the Council of 12 August 2013 on attacks against information systems [2013] OJ L218/8
49.	2014	[E-Identification and Trust Regulation (eIDAS Regulation)] Regulation (EU) 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC [2014] OJ L257/73
50.	2014	[Collective Management of Copyright Directive] Directive 2014/26/EU of the European Parliament and of the Council of 26 February 2014 on collective management of copyright and related rights and multi-territorial licensing of rights in musical works for online use in the internal market [2014] OJ L84/72
51.	2014	[Radio Equipment Directive] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [2014] OJ L 153/62

52.	2015	[Directive on the provision of information in the field of technical regulations and of rules on Information Society services] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services [2015] OJ L 241/1
53.	2015	[Connected Continent Regulation] Regulation (EU) 2015/2120 of the European Parliament and of the Council of 25 November 2015 laying down measures concerning open internet access and amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services and Regulation (EU) No 531/2012 on roaming on public mobile communications networks within the Union [2015] OJ L310/1
54.	2015	[Payment Services Directive (2); PSD2] Directive 2015/2366/EU of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) 1093/2010, and repealing Directive 2007/64/EC [2015] OJ L337/35
55.	2016	[Police and Criminal Justice Authorities Directive] Directive 2016/680/EU of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA [2016] OJ L119/89

56.	2016	[General Data Protection Regulation (GDPR)] Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data [2016] OJ L119/1
57.	2016	[Cybersecurity Directive (also known as 'NIS Directive')] Directive 2016/1148/EU of the European Parliament and of the Council concerning measures for a high common level of security of Network and Information Systems across the Union [2016] OJ L 194/1
58.	2017	[Proposal e-Privacy Regulation] Proposal for a Regulation of the European Parliament and of the Council concerning the respect for private life and the protection of personal data in electronic communications and repealing Directive 2002/58/EC, COM(2017) 10 final
59.	2017	Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L 117/1
60.	2017	[Roaming Regulation] Regulation (EU) 2017/920 of the European Parliament and of the Council of 17 May 2017 amending Regulation (EU) No 531/2012 as regards rules for wholesale roaming markets [2017] OJ L 147/1 (currently no longer in force)
61.	2018	[Audio-visual Media Services Directive] Directive (EU) 2018/1808 of the European Parliament and of the Council of 14 November 2018 amending Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audio-visual media services (in view of changing market realities) [2018] OJ L 303/69

62.	2018	[European Electronic Communications Code Directive] Directive (EU) 2018/1972 of the European Parliament and of the Council of 11 December 2018 establishing the European Electronic Communications Code (Recast) [2018] OJ L 321/36
63.	2019	[Regulation for contract summary] Commission Implementing Regulation (EU) 2019/2243 of 17 December 2019 establishing a template for the contract summary to be used by providers of publicly available electronic communications services pursuant to Directive (EU) 2018/1972 of the European Parliament and of the Council [2019] OJ L 336/274
64.	2019	[Cybersecurity Act] Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 [2019] OJ L 151/15
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66.	2019	Directive (EU) 2019/789 of the European Parliament and of the Council of 17 April 2019 laying down rules on the exercise of copyright and related rights applicable to certain online transmissions of broadcasting organisations and retransmissions of television and radio programs, and amending Council Directive 93/83/EEC [2019] OJ L 130/82
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68.	2019	[Regulation on online platform-to-business relationship] Regulation (EU) 2019/1150 of 20 June 2019 on promoting fairness and transparency for business users of online intermediation services [2019] OJ L 186/57
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74.	2020	[NIS2 Directive (proposal)] Proposal for a Directive of the European Parliament and of The Council on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148, COM(2020) 823 final
75.	2020	[Digital Services Act] Proposal for a Regulation of the European Parliament and of the Council on a Single Market for Digital Services and amending Directive 2000/31/EC, COM(2020) 825 final

76.	2020	Proposal for a Directive of the European Parliament and of the Council on the resilience of critical entities, COM(2020) 829 final
77.	2020	[Digital Markets Act (proposal)] Proposal for a Regulation of the European Parliament and of the Council on contestable and fair markets in the digital sector, COM(2020) 842 final
78.	2021	Regulation (EU) 2021/887 of the European Parliament and of the Council of 20 May 2021 establishing the European Cybersecurity Industrial, Technology and Research Competence Centre and the Network of National Coordination Centres [2021] OJ L 202/1
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80.	2021	Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 910/2014 as regards establishing a framework for a European Digital Identity, COM(2021) 281 final
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86.	2022	[European Health Data Space (proposal)] Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM(2022) 197 final
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Colophon

design
Beelenkamp ontwerpers, Tilburg
photography cover
Maurice van den Bosch
layout and printing
Studio | powered by Canon