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IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020

{COM(2022) 454 final} - {SEC(2022) 321 final} - {SWD(2022) 283 final}

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1. INTRODUCTION: EU POLITICAL AND LEGAL CONTEXT

In a more and more digitalised world, the number of high-profile cyberattacks keeps on increasing and the global annual cost of cybercrime was estimated to amount to EUR 5.5 trillion by 2021.[1]

Digital hardware and software products constitute one of the main avenues for successful cyberattacks. In a connected environment, a cybersecurity **incident in one product can affect an entire organisation or a whole supply chain, often propagating across the borders of the internal market within a matter of minutes**. This can lead to severe disruption of economic and social activities or even become life threatening. While the cybersecurity of providers of digital services is regulated at EU level under the Directive concerning measures for a high common level of security of network and information systems across the Union (**'NIS Directive'**),[2] the security of products with digital elements and in particular of software products is so far not subject to any comprehensive piece of EU regulation.

> ***Products with digital elements (examples):*** *End devices, e.g.: laptops, smartphones, sensors and cameras; smart robots; smart cards; smart meters; mobile devices; smart speakers; routers; switches; industrial control systems + Software: firmware; operating systems; mobile apps; desktop applications; video games + Components (both hardware as well as software): computer processing units; video cards; software libraries.*

There are numerous examples of noteworthy cyberattacks resulting from suboptimal product security, such as the **Pegasus** spyware, which exploits vulnerabilities in mobile phones and has been used by governments to spy on critics and opponents, as well as against prominent political leaders in Europe;[3] the **WannaCry** ransomware worm, which exploited a Windows vulnerability that affected 200 000 computers across 150 countries in 2017 and caused a damage amounting to billions of USD;[4] the **Kaseya VSA supply chain attack**, which used Kaseya's network administration software to attack over 1 000 companies and forcing a supermarket chain to close all its 500 shops across Sweden;[5] or the many incidents in which **banking applications are hacked** to steal money from unsuspecting consumers.

The **EU framework** comprises several pieces of horizontal legislation that cover certain aspects linked to cybersecurity from different angles (products, services, crisis management, and crimes), including measures to improve the security of the digital supply chain. In 2013, the Directive on attacks against information systems,[6] harmonising criminalisation and penalties for a number of offences directed against information systems came into force. In August 2016, the **NIS Directive** entered into force as the first piece of EU-wide legislation on cybersecurity. It introduced obligations on entities operating in key sectors of the European economies and societies, with a view to make them more resilient against cyber-attacks. More recently, the Commission proposed a review of this Directive ('NIS2 Directive proposal'),[7] which will most likely enter into force in 2022.[8] The upcoming NIS2 Directive raises the EU common level of ambition, through a wider scope, clearer rules, stronger supervision tools, a strengthened framework for operational capabilities and crises management and increased information sharing and cooperation. The new upcoming Directive also provides for **supply chain security obligations** and related risk management measures. In 2019, the **EU Cybersecurity Act**[9] entered into force, aiming to enhance

[1] European Commission Joint Research Centre (2020): "Cybersecurity – Our Digital Anchor, a European perspective", page 7.

[2] Directive (EU) 2016/1148 (NIS Directive).

[3] For example: the Spanish Prime Minister: https://www.theguardian.com/world/2022/may/02/spain-prime-minister-pedro-sanchez-phone-pegasus-spyware.

[4] https://www.reuters.com/article/us-cyber-attack-europol-idUSKCN18A0FX.

[5] https://www.bleepingcomputer.com/news/security/coop-supermarket-closes-500-stores-after-kaseya-ransomware-attack/.

[6] Directive 2013/40/EU.

[7] NIS2 proposal, COM(2020) 823 final.

[8] A provisional political agreement was reached in mid-May 2022.

[9] Cybersecurity Act: Regulation (EU) 2019/881.

the security of ICT products, services and processes by introducing a voluntary certification mechanism.[10]

Cybersecurity of the entire ecosystem is ensured only if all its components are cyber-secure. The above-mentioned EU legislation has however substantial gaps in this regard, as it does not cover the security of products with digital elements (see gap analysis in *Annex 13*).

Improving the cybersecurity of key services through the NIS Directive will **not be enough to effectively improve cybersecurity throughout the supply chain**. Nor the voluntary cybersecurity certification schemes issued under the Cybersecurity Act where manufacturers do not have a legal obligation to certify their products would be enough to affectively address cybersecurity challenges.

The **current EU framework[11] applicable to products** that may also have digital elements comprises several pieces of legislation, including EU legislation on specific products covering safety-related aspects and general legislation on product liability. However, the current legislation covers only certain aspects linked to the cybersecurity of tangible products with digital elements and, where applicable, embedded software[12] concerning these products (e.g. Radio Equipment Directive – RED – and its relevant delegated act[13]). The EU regulatory framework on products (e.g. the General Product Safety Directive (GPSD) and the Machinery Directive (MD), both currently under review) does not prescribe comprehensive specific cybersecurity requirements.

These findings were also confirmed by an exploratory study contracted by the Commission and conducted in 2020-2021 to assess the need for horizontal cybersecurity requirements for products with digital elements, which also indicated that the benefits of the regulatory intervention would outweigh its potential costs.[14] A follow-up study[15] was also contracted by the Commission in early 2022, supporting this impact assessment.

While commonly accepted that an incident concerning products with digital elements can affect the whole system, it also appears more and more likely that the market will not be able to meet these constantly rising cybersecurity risks without an appropriate intervention from the policy makers.

At **global level**, security of supply chain and security of products with digital elements became prominent in recent years. Given that most products with digital elements are sold globally and not only within specific countries (for example, most organisations worldwide are using the same operating systems and a majority of smartphones across the globe is outfitted with the same types of microprocessor), the problems associated with the security of products with digital elements as described in the problem definition of this report are not specific to the EU but impact the rest of the world too. While cybersecurity product regulation is almost non-existing across the globe, several countries around the world have started to introduce measures (mainly voluntary) to address this issue. One of the most comprehensive sets of measures was taken by the Unites States of America as a result of significant supply chain attacks that affected the US administration. The measures focus on software and range from guidelines establishing best practices to detect vulnerabilities to requirements for critical software delivered to government customers or a pilot program on cybersecurity labelling for Internet of Things (IoT) products. The UK is re-evaluating supply chain risks linked to ICT services and software and considering introducing soft law or regulatory measures. In Asia, various approaches are considered for supply chain security, such as

[10] The Cybersecurity Act allows the development of dedicated certification schemes. Each scheme establishes and lists the relevant standards. The decision to develop a cybersecurity certification is a risk-based one.

[11] Mainly New Legislative Framework (NLF) legislation. See for more details *Annex 11.*

[12] Software directly supportive to the function of the device on which the software is downloaded.

[13] C(2021) 7672 final supplementing RED, with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of the Radio Equipment Directive (RED).

[14] https://digital-strategy.ec.europa.eu/en/library/study-need-cybersecurity-requirements-ict-products.

[15] Study by Wavestone, CEPS and ICF supporting the Commission preparatory work for the Cyber Resilience Act.

a potential IoT security framework in Japan or cybersecurity labelling schemes of the likes of those recently introduced in Singapore. For more details on these global developments see *Annex 6*.

Noting the above-mentioned gaps in the EU legislative framework, various programmatic and political documents have called for **specific EU cybersecurity requirements for digital or connected products**.

The need for horizontal cybersecurity requirements for all products with digital elements on the internal market as the missing piece of the puzzle completing the picture of EU cybersecurity policies was not only identified in the context of development and implementation of recent EU cybersecurity legislation but also by relevant strategic and programmatic documents: The EU's Cybersecurity Strategy for the Digital Decade[16] of 16 December 2020 had already announced the establishment of common European cybersecurity standards for connected products. In her 2021 State of the Union address,[17] President von der Leyen announced a new European Cyber Resilience Act (CRA), planned for Q3/2022 under the Commission Work Programme 2022. Council Conclusions of 2 December 2020[18] and of 23 May 2022[19] have called for "*a horizontal regulation introducing cyber-security requirements*" covering "*the whole lifecycle of products with digital elements*". The European Parliament, in its Resolution of 10 June 2021,[20] welcomed *"the Commission's plans to propose horizontal legislation on cyber-security requirements for connected products and ancillary services"*.

A horizontal intervention would put in place a framework for improving the security of products with digital elements. It would require manufacturers of hardware and software to take cybersecurity measures and improve transparency. This will reduce the number of vulnerabilities in such products and empower users to choose products matching their security needs and to use these products in a secure manner. It would aim to be one building block in the EU's endeavor to ensure a high level of cybersecurity throughout different supply chain levels, as well as in relation to its key concerned actors. At the same time, it would take a coherent and effective approach to preventing and countering cybercrime, all these ultimately for the benefit of consumers and citizens.

In the run-up to this impact assessment, the Commission has extensively consulted all relevant stakeholders. Member States, manufacturers, users, and other stakeholders were also invited to participate in the Open Public Consultation and in the surveys and workshops organised by the study supporting the Commission preparatory work for the upcoming regulatory intervention.[21] The Commission has also published a Call for Evidence, to which stakeholders could submit feedback. See also *Annex 2* on stakeholder consultation.

2. PROBLEM DEFINITION

2.1. What are the problems and what are their consequences?

Cybersecurity in products with digital elements is characterised by two major problems leading to a wide range of consequences and in particular to costs for users, both organisations and consumers, and society as a whole, mainly: (1) a **low level of cybersecurity of products with digital elements**, which is primarily reflected by the widespread prevalence of vulnerabilities and the insufficient and inconsistent provision of security updates, but also (2) an **insufficient understanding among users as regards the cybersecurity of products** because they are often

[16] JOIN(2020) 18 final.
[17] https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_4701.
[18] See full text here.
[19] https://www.consilium.europa.eu/media/56358/st09364-en22.pdf.
[20] 2021/2568(RSP).
[21] Study by Wavestone, CEPS and ICF supporting the Commission preparatory work for the Cyber Resilience Act.

not provided with the information necessary to choose products with appropriate cybersecurity features or to use products in a secure manner, leading to inadequately configured products.

The cybersecurity of products with digital elements has a particularly strong **cross-border dimension**, as products manufactured in one country (including third-countries), such as operating systems or laptops, are often used by organisations and consumers across the entire internal market. In addition, given the borderless nature of the Internet, incidents initially affecting only a single entity or a single Member State often spread within minutes across the entire internal market.

The widespread presence of vulnerabilities in products with digital elements used by organisations, such as critical infrastructure, or by consumers, as well as misconfigured products due to the users' inadequate choice of security settings,[22] have far-reaching consequences. Businesses and other organisations bear significant cost associated with mitigating the risks related to cybersecurity. In addition, they must respond to and recover from cyberattacks, which often propagate across national borders and throughout the internal market. There is also a cost to society when digital solutions are not taken up for fear of security risks. Finally, there is a risk that Member States may start to regulate products security at national level, leading to internal market fragmentation.

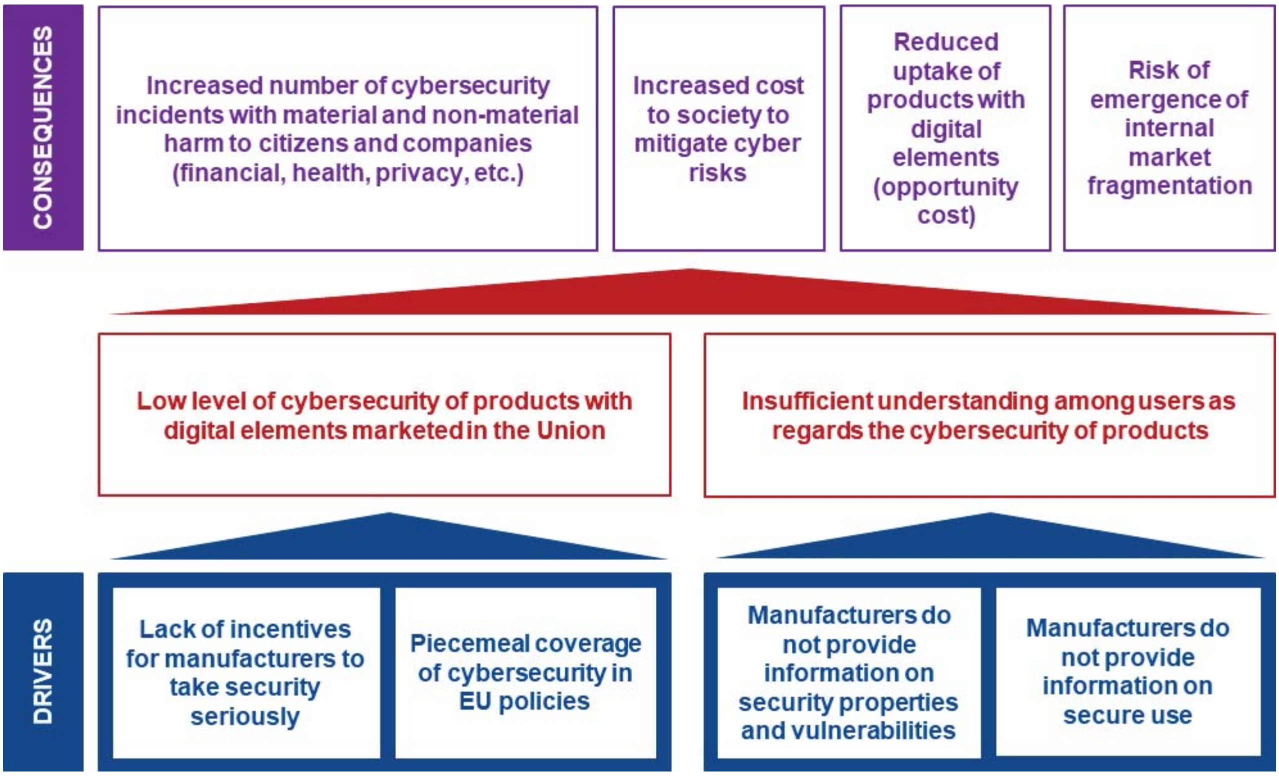
CONSEQUENCES
Increased number of cybersecurity incidents with material and non-material harm to citizens and companies (financial, health, privacy, etc.)
Increased cost to society to mitigate cyber risks
Reduced uptake of products with digital elements (opportunity cost)
Risk of emergence of internal market fragmentation
Low level of cybersecurity of products with digital elements marketed in the Union
Insufficient understanding among users as regards the cybersecurity of products
DRIVERS
Lack of incentives for manufacturers to take security seriously
Piecemeal coverage of cybersecurity in EU policies
Manufacturers do not provide information on security properties and vulnerabilities
Manufacturers do not provide information on secure use

Figure 1: Problem definition

While fewer vulnerabilities in products with digital elements and more transparency on the side of manufacturers as regards the security properties and secure use of products would not eliminate such costs altogether, more secure hardware and software and better documentation and instructions could lead to a notable reduction in costs. Given that most attacks rely on vulnerability exploits, there would be fewer incidents to manage and recover from. If incidents became less likely, a number of risk mitigation measures, such as cybersecurity insurance, could become less expensive.[23]

[22] From a cybersecurity perspective, a product with digital elements is misconfigured if the security settings chosen by the user do not adequately reflect the user's security requirements, leading to an increased attack surface and a higher risk of incidents.

[23] Insurers gather information about hardware and software vulnerabilities to improve their risk models and calculate risk premiums. See https://assets.kpmg/content/dam/kpmg/xx/pdf/2017/07/cyber-insurance-report.pdf, p. 10.

2.1.1. Problem 1: Low level of cybersecurity of products with digital elements marketed in the Union

The vast majority of attacks on critical infrastructure or other essential services are the result of vulnerabilities in products with digital elements. The Commission's proposal for a revision of the NIS Directive requires companies to integrate supply chain security measures into their risk management processes. However, the security of such entities also depends a lot on the availability of secure products. Even the most diligent risk management process cannot offer a high level of organisational security if the market for products with digital elements does not cater to the security needs of organisations.

While a number of factors, such as badly configured systems and credential theft (e.g. through phishing), can facilitate or enable cyberattacks, the main attack vector for security breaches is the **exploitation of vulnerabilities in hardware and software**. Estimates of the share of incidents resulting from exploits against weaknesses in the computational logic and design of software range from 62 %[24] for operators of essential services identified under the NIS Directive to 90 %.[25] A large majority of vulnerabilities are exploitable over the Internet and do not require physical access to networks,[26] which explains why malicious actors are carrying out their attacks on European organisations from anywhere in the world.

Cyberattacks against individuals or organisations exploit vulnerabilities in software and hardware products deployed within the victim's network. To achieve their mission, malicious actors usually exploit multiple vulnerabilities at various stages of an attack[27] .[28] Preventing vulnerabilities during product development and identifying and closing vulnerabilities in products before they can be exploited could bring cyberattacks to halt at various stages of their development. For example, attackers might first exploit a vulnerability allowing them to breach the server hosting a company's website before making their way through the company's network to more crucial systems, such as key workstations and the sensitive data stored thereon.

The number of vulnerabilities recorded in vulnerability databases is increasing year-on-year. For example, vulnerabilities recorded under the US Common Vulnerabilities and Exposures (CVE) system have increased from 18 325 in 2020 to 20 150 in 2021. This is also valid for the high-profile vulnerabilities that are exploited by malicious actors and for which manufacturers have to date not provided any patch ("zero-days"). According to cybersecurity researchers and databases tracking vulnerabilities, to date the year 2021 has seen the so-far highest number of zero-day vulnerabilities in products with digital elements actively exploited.[29] As a result, the attack surface that malicious actors can exploit increased significantly. At the same time, the threat landscape has evolved, with the number of documented major state-sponsored cybercrime groups[30] increasing year-on-year.[31]

[24] Calculation based on the preliminary results of a still ongoing survey commissioned by ENISA and executed by Gartner (2022): NIS Investments Study 2022.

[25] Hao Wang and Andy Wang (2009): Security metrics for software systems, ACM-SE 47: Proceedings of the 47th Annual Southeast Regional Conference, p. 1.

[26] Gueye and Mell (2021): "A Historical and Statistical Study of the Software Vulnerability Landscape", *The Seventh International Conference on Advances and Trends in Software Engineering SOFTENG 2021*, p. 1.

[27] During the *initial reconnaissance* stage, attackers search for weaknesses in the victim's systems, including vulnerabilities in hardware and software. Exploiting vulnerabilities not only facilitates the *initial compromise* of a victim's systems but also allows an attacker to gain full control of a system and *move* to other systems within an organisation or network.

[28] For a snapshot of the distribution of recorded vulnerabilities across the various stages and techniques of an attack see Ampel, Samtani, Ullman and Chen (2021): "Linking Common Vulnerabilities and Exposures to the MITRE ATT&CK Framework: A Self-Distillation Approach", *2021 ACM Conference Knowledge Discovery and Data Mining*.

[29] For example, as of September 2021, the Zero-day tracking project had recorded 66 zero-days in use, as compared with just 37 in 2020. Source: https://www.technologyreview.com/2021/09/23/1036140/2021-record-zero-day-hacks-reasons/

[30] So-called advanced persistent threats (APT).

[31] See article here.

While there is no universally applicable measurement of the aggregate level of security of products with digital elements marketed in the Union, a number of observations indicate that the **security of products with digital elements is low across the board**.

Vulnerabilities are regularly identified in all types of products, both hardware and software. When it comes to hardware, vulnerabilities are discovered both in integrated products sold in the market (such as smartphones, laptops or smart household appliances) as well as in hardware components, such as in memory, central processing units (CPUs) and other chipsets. Similarly, software vulnerabilities are found in all types of products, ranging from operating systems to user applications and even those products actually designed to help prevent incidents, such as anti-virus software.[32] Again, vulnerabilities are not only found in final products but also in intermediate software components, such as libraries, and including in open-source components. The Apache Log4j logging utility is the most recent example of a major vulnerability in a widely used open-source software component that has affected entities across the entire internal market. Log4j has been used by a wide range of major software manufacturers and the vulnerability, which has existed since 2013 but was only discovered in 2021, has led to security incidents across the globe.[33]

Moreover, the number of vulnerable devices connected to the Internet is increasing. For example, manufacturers are connecting more and more ICSs to the Internet. Between 2017 and 2018, the number of ICSs increased by 27 %.[34] According to a 2021 study, many companies are connecting operational technology (OT) directly to the Internet. Almost all devices analysed by the study contain at least one vulnerability, with Europe and North America being the most affected.[35]

Security is not only a concern in products deployed in an industrial or organisational setting, but also when it comes to consumer devices. A recent Euroconsumers probe into connected home devices, such as alarm systems and food processors, has revealed that two-thirds of devices contain vulnerabilities considered as ‘of high severity’ or ‘critical’, affecting both low-cost devices of unknown brands as well as products developed by well-known manufacturers.[36] Vulnerabilities in connected products are not only a theoretical concern, but their exploitation has a very real impact on consumers. For example, in 2019 cybercriminals breached Ring Home Security Cameras to observe citizens in their private homes and to speak with a small child in the child’s room.[37]

Manufacturers of products with digital elements do not only place vulnerable products on the market, but they often also do little to improve security throughout the **life cycle** of their products. For example, a 2018 survey of smartphone manufacturers revealed that 14 out of 19 device manufacturers provide security updates for less than three years.[38] In addition, when manufacturers do provide updates fixing vulnerabilities, they often take too long. Even security flaws discovered by Google’s Project Zero, which pressures manufacturers of browsers and other software into swiftly fixing vulnerabilities by threatening to disclose them after 90 days, are on average only fixed after 52 days.[39]

Finally, many manufactures do not even provide for means to contact them to report discovered vulnerabilities. Weaknesses in products with digital elements are not only discovered by the

[32] https://thehackernews.com/2020/10/antivirus-software-vulnerabilities.html

[33] https://security.googleblog.com/2021/12/understanding-impact-of-apache-log4j.html

[34] https://www.ptsecurity.com/ww-en/analytics/ics-vulnerabilities-2019.

[35] Simon Daniel Duque Anton, Daniel Fraunholz, Daniel Krohmer, Daniel Reti, Daniel Schneider, and Hans Dieter Schotten (2021): “The Global State of Security in Industrial Control Systems: An Empirical Analysis of Vulnerabilities around the World”, *IEEE Internet of Things Journal*, Volume: 8, Issue: 24, Dec.15, 15 2021.

[36] Euroconsumers (2021) *“Hackable home project: Euroconsumers unveils worrying results for smart device owners”*

[37] BBC (2019) https://www.bbc.com/news/technology-50760103.

[38] SecurityLab (2018), see the table here.

[39] Google Project Zero (2022).

manufacturer of a product or a malicious actor, but also by other manufacturers,[40] security researchers, ethical hackers and even customers. Ideally, organisations should therefore develop their own vulnerability disclosure policies to facilitate interaction with these actors.[41] At the very least, organisations should provide for a means to report vulnerabilities to them.[42] According to the European Telecommunications Standards Institute, *"As of early 2022 only about only about 20 % of ICT and IoT companies have a publicly identifiable dedicated means to notify a company of a potentially serious security issue with their products or services."*[43]

The problems associated with non-secure products are exacerbated by the fact that in a range of markets for products with digital elements, the number of available products is very limited, creating a *monoculture*. As a result, whenever a new vulnerability is exploited, a relatively large number of users is affected at the same time. This monoculture is explained by the fact that in some instances the utility of products with digital elements, in particular software, increases with the number of people that use it. The importance of such *network effects* that dissuade users from diversifying the products that they use and their impact on cybersecurity have been long recognised.[44]

In addition, exploiting known vulnerabilities has never been easier and does often not require a particularly high degree of familiarity with the underlying weaknesses in the computational logic of targeted systems.[45]

Asked to rate the overall level of security of products with digital elements in the Union, the respondents to the Commission's public consultation on the initiative gave on average a 2.82 (on a scale from 1 to 5 with 5 indicating a very high level of cybersecurity)products with digital elements. The responses of the different stakeholder groups were as follows: national market surveillance bodies (1.5), consumer associations (1.7), public administrations as users (2.5), SMEs as users (2.5), hardware manufacturers (3.2), software manufacturers (2.8), SMEs in their role as manufacturers (3.2). In addition, an overwhelming majority of 95 % of respondents said that the level of risk of cybersecurity incidents affecting products with digital elements has increased during the last five years.

2.1.2. Problem 2: Insufficient understanding among users as regards the cybersecurity of products

While it is crucial to make products with digital elements more secure, cybersecurity incidents are in many cases also the result of users choosing products ill-fitted for their purposes or wrongly configuring hardware and software, thereby unnecessarily increasing the security risk of their device or network. This is the result of a number of factors, including a lack of cybersecurity awareness and skills of users, and a lack of information provided by manufacturers on security properties, vulnerabilities and secure use. For example, a study of a Dutch consumer protection organisation covering 86 manufacturers across 18 different product groups has revealed that only 1 out of 5 manufacturers provides information to customers about available security updates.[46]

[40] Some companies employ security analysts tasked with discovering vulnerabilities in products with digital elements of other manufacturers, such as for example Google's Project Zero, which reports vulnerabilities to manufacturers first and publishes them after a 90 day period.

[41] For example, by implementing EN ISO/IEC 29147, which provides requirements and recommendations to manufacturers on the disclosure of vulnerabilities in products and services.

[42] A popular standard is security.txt, a plaintext document that is placed on a manufacturer's website and which contains contact information for reporting vulnerabilities in a secure manner.

[43] See ETSI press release on the coordinated vulnerability disclosure report

[44] For an extensive discussion of the phenomenon, see Geer, Schneider et al (2003): "CyberInsecurity: The Cost of Monopoly", Computer & Communications Industry Association Report.

[45] Popular frameworks used by security analysists as well as by malicious actors contain thousands of vulnerability exploits that can be used out of the box to breach unpatched systems. For example, the Metasploit Framework, a popular penetration testing suite, contains almost 600 exploit modules to target systems running Linux, the most widely-used operating system for servers, as well as more than 1300 exploit modules that could be used to breach into Microsoft Windows installations.

[46] https://www.consumentenbond.nl/nieuws/2022/fabrikanten-informeren-onvoldoende-over-updates

Nothing is more revealing of the lack of understanding amongst users than the notorious neglect of urgent security updates. A survey from 2014 interviewing Microsoft Windows users suggested a lack of awareness and knowledge by users as well as a lack of clear information provided by manufacturers to users.[47] According to 2020 Eurostat data, around 48 % of EU citizens have never restricted or refused access to personal data, when using or installing an app on a smartphone.[48]

Asked in the consultations held by the study supporting this impact assessment to which extent an insufficient understanding of users of the security of products with digital elements has a negative impact on the security of individuals or organisations, 69 % of participants replied that the impact was at least moderate. Asked to rate consumers' awareness and understanding of cybersecurity properties of products with digital elements, consumer organisations gave an average rating of 2.33 (on a scale from 1 to 5). Asked in the public consultation to rate their own awareness of the cybersecurity risks associated with products with digital elements, consumer organisations gave a rating of 2.3 on behalf of consumers. Similarly, when asked to rate their understanding of the cybersecurity properties of products with digital elements and the skills to operate them securely, consumer organisations provided a rating of 1.7.

2.2. What are the problem drivers?

2.2.1. Driver 1: Lack of incentives for manufacturers to take security seriously

Manufacturers often neglect the security of their products. Almost 50 % of manufacturers knowingly place products with digital elements on the marked that contain vulnerabilities.[49] One of the main reasons for this is that manufacturers lack the necessary incentives to invest in a secure development life cycle (SDLC). This is the result of strong negative externalities in markets for products with digital elements, information asymmetries between manufacturers and users, a faced-paced market and the costs associated with secure development.

A recent international survey amongst almost 100 software development professionals of mobile health applications has revealed that *"little or no budget for employing security"* is considered the main challenge when it comes to application security, followed by *"insufficient security knowledge [amongst developers]"*. Other important challenges that were identified highlight deficiencies in the development life cycles of manufacturers, such as a *"lack of involvement of security experts"*, *"poor security decisions during development process"* and a *"lack of security testing"*.[50]

Asked in the public consultation whether manufacturers of software were effectively addressing cybersecurity vulnerabilities and incidents affecting their customers, the respondents gave an overall rating of 2.96 (on a scale from 1 to 5),[51] with consumer organisations rating the effectiveness of manufacturers very low (1.33). The responses of the other stakeholder groups were as follows: national market surveillance bodies (2.0), public administrations as users (2.8), SMEs as users (2.3), hardware manufacturers (3.7), software manufacturers (3.4), SMEs in their role as manufacturers (3.5).

Users bear the costs associated with incidents and the market has negative externalities

While manufacturers of products with digital elements can sometimes face reputational damage when their products are found to be lacking security, the cost of vulnerabilities is predominantly borne by the users, such as operators of essential services, but also consumers. Examples of costs

[47] K. E. Vaniea, E. Rader, and R. Wash (2014): "Betrayed by updates: How negative experiences affect future security", *Proceedings of the 32nd Annual ACM Conference on Human Factors in Computing Systems*.

[48] https://ec.europa.eu/eurostat/databrowser/view/ISOC_CISCI_SP20/default/bar?lang=en&category=isoc.isoc_i.isoc_ci_sci

[49] Security (2020): "Survey reveals nearly 50% of organizations knowingly push vulnerable software".

[50] Aljedaani, Ahmad, Zahedi and Babar (2020): "An Empirical Study on Developing Secure Mobile Health Apps: The Developers' Perspective", *2020 27th Asia-Pacific Software Engineering Conference (APSEC)*, p. 5.

[51] Respondents identified as users gave a rating of 2.66, while software manufacturers rated their measures with 3.43. Small and medium sized manufacturers provided a slightly higher rating of 3.53.

borne by users are risk mitigation costs, such as taking out cybersecurity insurance[52] or putting in place a security operation centre, as well as the costs resulting from a cybersecurity incident, such as the cost involved in recovering lost data. This limits the incentives of manufacturers to invest into secure design and development and to provide security updates.[53]

While it might seem intuitive to assume that manufacturers have an incentive to make their products secure and avoid the fallout of incidents involving their products, in reality it is rarely the companies affected by major cybersecurity incidents that suffer significant negative long-term consequences, but rather the users or customers.[54] One of the reasons why reputational damage often does not translate into users actually switching products consists of the high switching costs associated with replacing a product by another one: products are often heavily tied into existing operations. Moreover, in many cases products markets do not provide for a wide range of alternative products with digital elements. For example, there are only very few widely used operating systems for desktop computers and smartphones. Similarly, the chipset market is highly concentrated with only few companies offering desktop CPUs, video card chipsets and other components.

Respondents to the public consultation have identified costs borne by users as an important driver for the low level of security of products with digital elements: Respondents rated the *"The user bears additional cost when affected by a cybersecurity incident"* with 4.13 (on a scale from 1 to 5). The responses of the different stakeholder groups were as follows: national market surveillance bodies (4.7), consumer associations (5.0), public administrations as users (4.6), SMEs as users (4.6), hardware manufacturers (3.4), software manufacturers (3.9), SMEs in their role as manufacturers (3.6).

In addition, it is often not even the manufacturers or the users bearing the costs of incidents but unrelated third parties, such as the victims of DDoS attacks carried out using infected devices: Given the structural and persistent nature of such negative externalities in the markets for products with digital elements, a recent study on IoT device security has concluded that "The costs of security failures are often borne by other stakeholders than the owners of the device or the manufacturers. So, there is a market failure here that justifies government intervention."[55]

Information asymmetries

While the manufacturers of products with digital elements are normally not bearing the cost associated with vulnerabilities, they would have to bear the additional cost of making their products more secure. This raises the question if there could be any other incentives leading to an adequate level of investment in product security, such as competitive advantage derived from placing products with a high level of security on the market.

However, users are often unaware of the security risks associated with products with digital elements. While they may attribute value to secure products, they do not have the knowledge to understand the value stemming from a product that has been developed with security considerations mind. In addition, given the complexity of products with digital elements and the fact that users usually do not have any knowledge of the internal workings of a product, it is very difficult for them to make purchasing decisions based on such properties. This leads to "bad

[52] The cost of cyber insurance is estimated to range from USD 650 to USD 2 357 for liability limits of USD 1 000 000 (i.e. EUR 950 0000) for companies with moderate risks: https://advisorsmith.com/business-insurance/cyber-liability-insurance/cost/.

[53] See Asghari, van Eeten and Bauer: "Economics of cybersecurity", in: Bauer and Latzer (2016): "Handbook on the Economics of the Internet", p. 267.

[54] Morgner and Benenson (2018): "Exploring Security Economics in IoT Standardization Efforts", *Workshop on Decentralized IoT Security and Standards (DISS) 2018*, p. 3.

[55] Rodríguez et al (2021): "Superspreaders: Quantifying the Role of IoT Manufacturers in Device Infections", *20th Annual Workshop on the Economics of Information Security (WEIS 2021)*, for a more detailed discussion of IoT consumer device security, p. 13.

products driving out good ones".[56] While *information asymmetry* applies to both professional users (such as critical infrastructure) as well as consumers, it is in particular the case for consumers. As a result, manufacturers cannot gain a competitive advantage from investing in the security of their products, such as by adopting a SDLC.

Cybersecurity as a potential barrier to fast market entry (first-mover advantage)

Not only do manufacturers lack positive incentives to invest in security, emphasising product security can sometimes even be detrimental to the success of an undertaking: In a competitive market, companies can only bear additional marginal cost stemming from cybersecurity if their competitors are taking investments in cybersecurity equally seriously, unless they can increase prices because users value the integration of additional security properties. Hardware and software, however, are often characterised by the presence of strong network effects and economies of scale, making markets for products with digital elements a *winner takes it all* economy.

Due to the fast-paced nature of markets for products with digital elements, manufacturers are usually trying to bring new products or features for existing products onto the market as quickly as possible, prioritising feature development and compatibility with existing products, treating the development of security properties as an afterthought:[57] "From the economic perspective of the manufacturers, there are less benefits in strongly securing IoT devices compared to the benefits that arise from shorter development cycles omitting these security measures."[58] Nothing epitomises the fast market entry approach more than the motto that Facebook had adopted in its early years of development: *Move fast and break things*.

Securing products comes at a cost

While it is possible to improve the security of products through investment, companies tend to shy away from the costs associated with building a SDLC. The cost associated with improving product security depends on both the maturity of the entity as regards cybersecurity as well as the level of ambition. According to a recent study on the cost of required security, the cost associated with the additional effort made to improve the security of software products is at least 19 % of the development costs, depending on the security objectives to be achieved.[59]

Traditionally, researchers believed that rational manufacturers should invest in cybersecurity (such as by setting up a SDLC), as it would be cheaper to prevent vulnerabilities in the first place than to fix them at a later stage (delayed issue effect).[60] More recently, however, researchers have begun to challenge this notion, bringing forward new evidence suggesting that patching security holes in a product at a later stage is no more expensive than resolving security issues early during development.[61] This further substantiates the view that, given the cost of cybersecurity, manufactures have no natural incentive to develop secure products.

2.2.2. Driver 2: Piecemeal coverage of cybersecurity in EU policies

Currently there are no specific cybersecurity requirements comprehensively and systematically applicable to all products with digital elements, hardware or software, accessing the internal market. Cybersecurity of software (embedded in hardware and upload-able or of generic use, i.e.

[56] Ross Anderson (2001): "Why Information Security is Hard – An Economic Perspective", *Seventeenth Annual Computer Security Applications Conference*, p. 6.
[57] Morgner, Mai, Koschate-Fischer et al (2020): "Security Update Labels: Establishing Economic Incentives for Security Patching of IoT Consumer Products", *2020 IEEE Symposium on Security and Privacy (SP)*, p. 429.
[58] Morgner and Benenson (2018), p. 4.
[59] Elaine Venson (2021): "The Effects of Required Security on Software Development Effort", A Dissertation Presented to the Faculty of the USC Graduate School University of Southern California.
[60] Tim Menzies, William Nichols, Forrest Shull, Lucas Layman (2017): "Are Delayed Issues Harder to Resolve? Revisiting Cost-to-Fix of Defects throughout the Lifecycle", *Empirical Software Engineering, Volume 22, Issue 4 August 2017*, pp 1903-1935.
[61] Tim Menzies et al. (2017): pp 1903-1935.

standalone[62]) in particular, of key importance for cybersecurity policies, is the least regulated even at the level of sector- or product-specific legislation with limited scope.

In order to effectively ensure the security of products as per the problems identified, **comprehensive and systematic cybersecurity requirements** applicable to all digital products, should entail as key minimum elements, that: (i) **cybersecurity is factored in the design and development** of the digital products and that due diligence is exercised by manufacturers on security aspects when designing and developing their products, (ii) **transparency** is ensured on cybersecurity aspects that need to be made known to customers and (iii) **security support (updates and handling of vulnerabilities)** are provided after the placement on the market.

Nonetheless, there is a small set of EU legal acts providing for product-related cybersecurity requirements. This is the case of the Radio Equipment Directive (RED)[63] together with a recently adopted delegated regulation,[64] which covers IoT devices outfitted with a radio interface, or the Medical Devices Regulation (MDR),[65] which covers both tangible medical products as well as software. In addition, there are a few European product laws that provide some rules regarding the cybersecurity of products, albeit only in a *partial* manner, such as the Toy Safety Directive (TSD).[66]

However, most hardware, such as wired IoT devices or computer components, including chipsets, memory chips or processors, as well as the vast majority of software products, such as operating systems, user applications, server software or software libraries, are not covered by any European legal act dealing with their cybersecurity.

The exploratory study contracted by the Commission and conducted in 2020-2021 to assess the need for horizontal cybersecurity requirements for products with digital elements, conducted a **gap analysis**[67] comparing the cybersecurity objectives set out in the Cybersecurity Act (Article 51)[68] against the identified cybersecurity-relevant requirements of **37 pieces of EU legislation** concerning products with digital elements. This included all legislation related to the New Legislative Framework (NLF), as well as legislation with a strong link with cybersecurity and data protection, which can affect indirectly and to a limited extent manufacturers (e.g. the eIDAS Regulation, General Data protection Regulation (GDPR), the NIS Directive, RED and GPSD).[69]

The NLF is a package of measures that streamline the obligations of manufacturers, authorised representatives, importers and distributors, improve market surveillance and boost the quality of conformity assessments. It also regulates the use of CE marking and creates a toolbox of measures for use in product legislation. This framework was introduced in 2008 to depart from the 'old approach' where technical legislation was going into great detail, usually motivated by a lack of confidence in the rigour of economic operators on issues of public health and safety.

The gap analysis concluded that the **current EU legislative framework does not cover all security objectives**, that legislation related to the **NLF does not address fully the cybersecurity requirements** for products with digital elements and that there are different levels of granularity of cybersecurity requirements in the legislation in scope. In addition, the study concluded that

[62] i.e. software that can be purchased by end users separately, such as operating systems; mobile apps; desktop applications; video games.

[63] Directive 2014/53/EU (RED).

[64] C(2021) 7672 final supplementing RED, with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of RED.

[65] Regulation (EU) 2017/745, (MDR).

[66] Directive 2009/48/EU, (Toy Safety Directive).

[67] Section 2.2 of the final report of the *Study on the need of Cybersecurity requirements for ICT products*, pages 52-61.

[68] To date, the Cybersecurity Act provides the most comprehensive set of cybersecurity requirements in EU law.

[69] The gap analysis used as a basis the Cybersecurity Act because it is one of the most recent, up-to-date, and relevant EU legislation that covers cybersecurity for products with digital elements at broad spectrum. The cybersecurity objectives of Article 51 also provide a comprehensive list of high-level cybersecurity requirements for products with digital elements, such as protection against unauthorised access or disclosure of information, or verification, or to follow the security by default principle.

requirements regarding software are very rarely covered by such legislation.[70] For more details on existing European legislation, see *section 1* in *Annex 5*.

As a result of the regulatory gaps described, no piece of EU legislation requires currently comprehensive cybersecurity requirements for all products with digital elements. While there is a variety of international standards concerning several aspects of product cybersecurity (consumer IoT, assurance of security throughout lifecycle or vulnerability handling, access control, etc.), there are no harmonised European standards for products with digital elements across sectors (*see Annex 14*).

A detailed regulatory gap analysis can be found in *Annex 13*.

2.2.3. Driver 3: Manufacturers do not provide information on security properties and vulnerabilities

Markets for products with digital elements exhibit strong information asymmetries.[71] This is in particular for closed source products,[72] but also applies to open source products,[73] given the high degree of complexity of products with digital elements. Against the backdrop of a user base that for the most part lacks the skills to evaluate the security properties of products with digital elements, manufacturers in products with digital elements markets are facing a *moral hazard*, being incentivised to further deprioritise product security and transferring the risk onto users.[74] This leads to a situation in which manufacturers compete with one another on product features, such design or usability, but not on advertised security properties. In many cases, the information provided by manufacturers does not even allow proficient users or companies, such as operators of essential services under the NIS Directive, to compare security requirements with security properties and to make informed purchasing decisions about products.[75] This is not only true when it comes to products with digital elements developed for end-users, but also with regard to intermediate software components used by other software manufacturers to build final products.[76]

Asked in the public consultation if they agreed with the statement that *"There is sufficient and clear information made available on the cybersecurity properties of products with digital elements"*, participants gave an average rating of 2.50 (on a scale from 1 to 5), with consumer organisations giving a rating of only 1.33, users (business and consumers) giving a rating of 2.34, hardware manufacturers rating the information they provide with 2.85. SMEs and organisations representing SMEs in general rated it at 2.4 and 2.6 out of 5, similar to the average, with a slightly higher rating of 3.00 for organisations representing SME manufacturers, and those representing SME users rating it at 2.0.

2.2.4. Driver 4: Manufacturers do not provide information on secure use

Apart from not disclosing relevant information about the security properties of products with digital elements, manufacturers often also fail to provide information helping users employ products in a secure manner, such as by including information on secure use in the manual or installation instructions. A recent survey of IoT device manufacturers revealed that only 43 % of manufacturers provide information on how users can change default passwords and only 26 % of

[70] Study supporting the Commission preparatory work for the Cyber Resilience Act – N° 2019-0024.

[71] Jeffrey Vagle (2017): "Cybersecurity and Moral Hazard", *Stanford Technology Law Review*, Vol. 23, 2020, p. 85.

[72] Closed source refers to software for which the manufacturer does not disclose the source code, making it extremely difficult to assess the functionality and security properties of a product.

[73] Open source refers to software for which the manufacturer discloses its source code to the public, allowing other manufacturers and security researchers to analyse the inner workings of a programme as well as its security properties.

[74] Jeffrey Vagle (2017): p. 87.

[75] Dutch Safety Board (2021): *"Vulnerable through software. Lessons resulting from security breaches relating to Citrix software"*, p. 89.

[76] Khan and Han (2006): "Assessing Security Properties of Software Components: A Software Engineer's Perspective", *Australian Software Engineering Conference (ASWEC'06)*, p. 1.

manufacturers provide additional advice on how to protect their products from cybersecurity breaches.[77]

2.2.5. *Additional drivers not addressed by this intervention*

In addition to the drivers listed above, there are a number of additional problem drivers that have an impact on the security of products with digital elements as well as on the understanding of users as regards such products. However, given the nature of the product-related intervention considered, these additional drivers would not necessarily be addressed directly.

- **Lack of bargaining power of users:** Products with digital elements markets are often characterised by the presence of a few large manufacturers due to *economies of scale* and *vendor lock-in*, the latter being the result of a lack of compatibility between hardware and software platforms. As a result, users of products with digital elements lack the bargaining power necessary to ensure that manufacturers develop products matching the security needs of specific users.

- **Lack of qualified security professionals:** Manufacturers of products with digital elements often struggle to hire qualified security professionals: For example, the gap in cybersecurity professionals in Europe amounted to 199 000 in 2020. The Union is trying to address the skills gap through a variety of measures, including funding through the Digital Europe Programme.

- **Lack of cybersecurity awareness and skills of users:** Studies show that users often lack even the most basic cybersecurity skills. While this applies in particular to consumers, who are often not even familiar with basic internet security terminology, it also affects businesses and other organisations: For instance, only half of business leaders and only a third of their employees acknowledge the risk that cybercrime poses to their organisations.

More details on additional drivers identified can be found in *section 2* of *Annex 5*.

2.3. Consequences of the problems identified

2.3.1. *Consequence 1: Increased number of cybersecurity incidents with material and non-material harm to citizens and companies*

The **importance and impact of cyberattacks** have increased dramatically in recent years. On the one hand, both companies and consumers are growing more dependent on products with digital elements. This trend has been exacerbated by the COVID-19 crisis, which gave rise to widely spread telework and accelerated the digitisation of society. In addition, critical infrastructure as well as manufacturers are increasingly connecting their industrial control systems (ICSs) to the Internet.[78] On the other hand, cyberattacks are sharply increasing and they are used as an economic and geopolitical weapon.[79]

The 2020 Annual Cost of a Data Breach Report of the Ponemon Institute estimates that the average **cost of a data breach** for individual businesses was EUR 3.5 million in 2018, which is an increase of 6.4 % over the previous year.[80] Such costs include, but are not limited to, getting systems and manufacturing processes back online, managing the reputational fallout, paying a ransom, recovering or compensating for lost or stolen data, and cleaning, reinstalling or replacing affected

[77] Rodríguez et al (2021) “Superspreaders: Quantifying the Role of IoT Manufacturers in Device Infections”, *20th Annual Workshop on the Economics of Information Security (WEIS 2021)*, for a more detailed discussion of IoT consumer device security, p. 9.

[78] https://www.ptsecurity.com/ww-en/analytics/ics-vulnerabilities-2019/

[79] Cyberattacks are performed by criminal groups as well as increasingly by nation state actors and other state-sponsored groups. Motives are manifold and include personal gain, cyber terrorism, signals intelligence and espionage, intellectual property theft as well as cyber warfare, often blending with conventional warfare.

[80] Annual Cost of a Data Breach Report, 2020, conducted by the Ponemon Institute, and based on quantitative analysis of 524 recent breaches across 17 geographies and 17 industries.

hardware. In many cases, it takes months for companies to fully recover from an incident.

As incidents affect the availability, integrity, authenticity and confidentiality of services, they often affect customers (e.g. a service might become unavailable or sensitive customer data might be stolen) and sometimes propagate across organisations and supply chains throughout the internal market, generating considerable costs. For example, ransomware attacks alone are estimated to have cost the world roughly USD 20 billion in the year 2021. Statistically speaking, every 11 seconds another organisation is hit by a ransomware attack.[81]

Supply chain attacks represented a major problem in recent years: cybercriminals introduce malicious code into legitimate products with digital elements for the purpose of attacking the users of such products.[82] One of the most prominent recent examples is the SolarWinds attack in 2020.

Vulnerabilities and badly configured systems not only affect the security of organisations but also have a major impact on consumers. Impacts can be financial, as well as related to privacy or health. For instance, when it comes to financial harm, certain types of malware infect the devices of citizens with the goal of collecting online banking credentials and secretly executing payments.[83] Incidents can also have an impact of the safety of citizens. For example, cybersecurity incidents in hospitals have been found to lead to a small increase in mortality rate.[84] In a number of instances, IoT consumer devices have been hacked to track the lives of citizens.[85]

A phenomenon of particular relevance to consumers is the hacking of IoT devices for the purpose of integrating them into a *botnet*, a larger network of devices stretching across the internal market and beyond, controlled by a malicious actor and used to conduct so-called DDoS attacks[86] affecting the availability of services provided by organisations, such as critical infrastructure, and to send out unwanted spam messages to email users. Cross-border botnets create significant negative externalities, as it is usually not the device owners that have to bear the cost of device abuse but rather the victims of DDoS attacks or the recipients of spam.[87] It is estimated that an individual small company targeted by a DDoS attack can face costs up to USD 120 000, while for larger companies the cost can go as high as USD 2 million.[88] In 2021 alone cybercriminals were able to leverage hacked devices and launch 9.75 million DDoS attacks worldwide.[89]

Generally speaking, entities across all economic sectors tend to fall victim to cybersecurity attacks. This is first and foremost explained by the fact that “in many cases the threats manifest themselves by exploiting vulnerabilities in underlying ICT systems that are being used in a variety of sectors”[90]. Nonetheless, certain sectors are more affected than others: According to the EU’s cybersecurity agency (ENISA), public administrations, digital service providers, healthcare and

[81] https://www.dataprivacyandsecurityinsider.com/2020/02/ransomware-attacks-predicted-to-occur-every-11-seconds-in-2021-with-a-cost-of-20-billion/.

[82] This once again raises the attention around supply chain attacks, which are often cross-border in nature. See https://www.enisa.europa.eu/publications/threat-landscape-for-supply-chain-attacks.

[83] For example, between 2007 and 2009 the ZeuS/Zbot trojan has infected computers globally by tricking users into downloading malicious content and by exploiting vulnerabilities. The crime group responsible for the trojan has allegedly stolen around 70 million USD, predominantly in the United States and United Kingdom. See Zhong et al (2015): “Stealthy Malware Traffic – Not as Innocent as It Looks”, *2015 10th International Conference on Malicious and Unwanted Software*.

[84] Choi and Johnson (2017): “Do Hospital Data Breaches Reduce Patient Care Quality?”, *Workshop on the Economics of Information Security 2017*.

[85] In 2019 household cameras sold by the company Ring were accessed, allowing hackers to observe citizens at home. In one case, an attacker addressed a child using a camera’s speakers. In 2021, a group of hackers gained access to the footage of Verkada cameras deployed in organisations, such as Tesla’s warehouses and factories, Cloudflare, health clinics and psychiatric hospitals.

[86] A malicious attempt to disrupt the normal traffic of a targeted server, service or network by overwhelming the target or its surrounding infrastructure with a flood of internet traffic.

[87] See Rodríguez, Noroozian, van Eeten and Gañá (2021): “Superspreaders: Quantifying the Role of IoT Manufacturers in Device Infections”, *20th Annual Workshop on the Economics of Information Security (WEIS 2021)*, for a more detailed discussion of IoT consumer device security.

[88] https://www.bulletproof.co.uk/industry-reports/2019.pdf, p. 20.

[89] https://www.helpnetsecurity.com/2022/03/28/ddos-attacks-2021.

[90] ENISA (2021): “ENISA Threat Landscape 2021. April 2020 to mid-July 2021”, p. 11.

finance are the sectors experiencing the highest number of incidents, while sectors such as water utilities, postal and courier services, space and semiconductors are the least affected.[91] These differences are explained by the relative economic importance of certain sectors as well as by the maturity of organisations when it comes to cyber resilience, an issue being addressed by the revision of the NIS Directive.

Respondents to the public consultation have overall rated the consequences of cybersecurity incidents as very high. SMEs consistently rated on average the material consequences of cybersecurity incidents higher than other organisations.[92]

2.3.2. *Consequence 2: Increased cost to society to mitigate cyber risks*

In addition to the costs following an incident, businesses and other organisations are also forced to invest significantly into incident prevention, handling and mitigation as a result of non-secure products with digital elements. Such investments include taking out cybersecurity insurance or putting in place entire company departments dedicated to security, such as cybersecurity incident response teams (CSIRTs) or security operations centres (SOCs). According to the Commission's impact assessment for the revision of the NIS Directive, the average ICT security spending of companies in 2020 is of approximately 9.14 % of their ICT spending.[93]

In the public consultation, both consumers as well as respondents identifying themselves as users agreed with the statement that *"The user bears additional costs due to highly priced cybersecurity insurance"*, rating it at 4.50 and 3.48 respectively (on a scale from 1 to 5). Similarly, consumers and users agreed with the statement that *"The user bears additional costs due to the need to deploy highly priced technical security solutions"*, rating it at 3.67 and 4.03 respectively. In particular SMEs in their role as users agreed with the two statements (3.80 and 4.20 respectively).

2.3.3. *Consequence 3: Reduced uptake of digital solutions*

Finally, lacking cybersecurity also creates *opportunity costs* for businesses, governments and society as whole, when modern technologies are not deployed as quickly as possible for fear of being unable to manage the risks associated with them. This may seem counterintuitive given the recent substantial increase in digitisation caused by the pandemic. But irrespective of the exceptional circumstances in recent years, security concerns are considered as one of the main barriers to the adoption of products with digital elements.[94] In fact, security concerns are one of the main reasons why decision makers are shying away from investments in IoT solutions.[95] A reduced uptake of digital solutions can have a negative impact on innovation, efficiency gains and, as a result, economic growth.

2.3.4. *Consequence 4: Risk of emergence of internal market fragmentation*

While only few Member States have so far introduced measures to regulate the security of products with digital elements at national level (both Germany and Finland have introduced labelling schemes, see *section 6.3*), the scale of the problems associated with insecure products with digital elements could in the future lead to targeted product-specific interventions at national level. The Council considers the security issues associated with products with digital elements as a matter of urgency and has repeatedly called upon the Commission to propose regulation in this area. Member States are aware that, given the impact on the internal market, measures need to be taken at EU level. In the absence of EU regulation however, they are likely to take further action, within then

[91] ENISA (2021), p. 13.

[92] The consequences regarded the financial cost of implementing measures to respond to a cybersecurity incident (3.81; 4.2 for SMEs), the financial cost of disruption (3.96; 4.6 for SMEs), the reputational damage of the affected entity (3.96; 4.2 for SMEs), the negative impact on the security of the economy and society as a whole (3.67; 4.4 for SMEs) and the damage to fundamental rights, such as privacy, data protection and consumer protection (3.80; 4 for SMEs). In comparison, the negative impact on health and life (2.71) and on the environment (2.31) were regarded as less severe.[92] This was also the case for SMEs.

[93] SWD(2020) 345 final, IA accompanying the NIS2 proposal, p. 71.

[94] This is the case in the health sector, where security concerns are a major barrier to the uptake of new technology. See here.

[95] See the IoT Large Scale Pilots eBook, p. 11.

limits allowed by the treaties. This could be the case particularly to achieve objectives in the areas of safety, health, environment and consumer protection, these being areas where national regulations of this sort could be acceptable without being considered a breach of free movement of goods in the internal market. This could lead to a situation in which manufacturers would be facing an unsystematic approach to product security across the internal market. This could result in internal market fragmentation with negative consequences for the cost-effectiveness and competitiveness of European hardware and software manufacturers (see *section 6.3*). In the public consultation, respondents rated the question *"To what extent do you agree that there is a risk of increasing costs and legal uncertainty for market stakeholders, in the absence of an EU initiative?"* with 4.38 out of 5 (with 5 indicating that they fully agree). SMEs responded with 4.4 out of 5, and organisations representing SMEs with 4.5.

Finally, in absence of harmonised rules, users, such as critical infrastructures obligated under the revised NIS Directive to take their supply chain security more seriously, may start putting in place diverging contractual requirements for manufacturers of products with digital elements.

2.4. How likely are the problems to persist?

There have been numerous efforts to improve the cybersecurity of products with digital elements both by academia and by the manufacturing and development community. For instance, new programming languages, such as Rust or Go, have been developed that minimize the risk of certain types of vulnerabilities, such as memory corruption. Several mostly large manufacturers have started adopting a SDLC with a view to improve software and hardware security. As a result, security software, such as static and dynamic testing tools, has become available on the market, helping manufacturers to verify the security of computer code. Moreover, some manufacturers of products, such as operating systems, browsers and routers, are outfitting their products with automated updating features, ensuring that also inexperienced users can benefit from the latest security updates.

In addition, the Cybersecurity Act, which came into force in 2019, provides for the possibility to certify, on a voluntary basis, ICT products, services and processes. A number of product-specific international standards have also emerged, such as ETSI's Consumer Mobile Device Protection Profile, standards for industrial automation and control systems,[96] or a set of guidelines released by the Open Web Application Security Project (OWASP).

Some of the problem drivers described in the previous section may diminish in the future. For example, the labour market may adjust and provide manufacturers with more qualified security professionals, either as a result of market forces or following government measures. Similarly, as a result of awareness raising campaigns and adapted school curricula, users could become more aware of cybersecurity risks and more proficient in using products with digital elements securely.

However, while some of the recent market developments and standardisation and certification efforts are steps in the right direction, most of the problem drivers are very unlikely to disappear, given that they are the **direct result of persistent structural market failures**. The lack of incentives for manufacturers to take the cybersecurity of their products seriously will persist in the presence of negative externalities and information asymmetries, but also against the backdrop of a fast-paced industry that rewards early market entry above everything else. Given that existing standards are voluntary and non-comprehensive, manufacturers have little incentive to apply them. In addition, while new supply chain security requirements for critical infrastructure and other essential entities under the reviewed NIS Directive[97] will help put pressure on hardware and software manufacturers, business users and other organisations, such as public administrations, will continue to lack negotiating power in more concentrated products with digital elements markets.

[96] Such as IEC 62443 .

[97] See Article 18 (2) (d) in COM/2020/823 final, NIS2 proposal.

While there have been various attempts within the market to improve the security of products with digital elements, the overall assessment that many products with digital elements are highly vulnerable is unlikely to change without government intervention. A recent study on software vulnerabilities has concluded that *"in 15 years, the vulnerability landscape hasn't changed; through the lens of the metrics in this paper we aren't making progress."*[98] As a result, regulators have little reason to believe that the situation will substantially improve without regulatory intervention.

In the absence of European legislation, Member States are likely to introduce national regulations laying down security requirements on such categories of products, within the limits allowed by EU law. While national intervention could contribute to reducing the problem of low product security, it would inevitably also lead to **internal market fragmentation**, preventing manufacturers on an otherwise global products market from providing hardware and software solutions across the internal market in a cost-effective manner (see *section 6.3* for more details).

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

This intervention will be based on Article 114 of the Treaty on the Functioning of the European Union (TFEU), whose objective is the establishment and functioning of the internal market by enhancing measures for the approximation of national rules. The measures must be intended to improve the conditions for the establishment and functioning of the internal market and must genuinely have that objective, actually contributing to the elimination of obstacles to the free movement of goods or services, or to the removal of distortions of competition.

Article 114 TFEU may be used as a legal basis to prevent the occurrence of these obstacles resulting from diverging national laws and approaches on how to address the legal uncertainties and gaps in the existing legal frameworks.[99] Furthermore, the Court of Justice has recognised that applying heterogeneous technical requirements could be valid grounds to trigger Article 114 TFEU.[100] The present intervention would aim to improve the internal market's functioning by streamlining and supplementing existing rules.

The current EU legislative framework applicable to products with digital elements is based on Article 114, and comprises several pieces of legislation, including on specific products and safety-related aspects or general legislation on product liability. However, it covers only certain aspects linked to the cybersecurity of tangible products with digital elements and, as applicable, software embedded in these products.

As explained in more detail in *section 6.3*, at national level, Member States are starting to take national measures requiring manufacturers of products with digital elements to enhance their cybersecurity. At the same time, the cybersecurity of products with digital elements has a particularly strong cross-border dimension, as products manufactured in one country are often used by organisations and consumers across the entire internal market. Incidents that initially concern a single entity or Member State often spread within minutes across organisations, sectors and several Member States.

The various acts and initiatives taken so far at EU and national levels only partially address the problems identified and risk creating a legislative patchwork within the internal market, increasing legal uncertainty for both manufacturers and users of these products and adding unnecessary burden on companies to comply with a number of requirements for similar types of products. Therefore, the envisaged intervention would harmonise and streamline the EU regulatory

[98] Gueye and Mell (2021), p. 6.

[99] CJEU Judgment of the Court (Grand Chamber) of 3 December 2019, Czech Republic v European Parliament and Council of the European Union, Case C-482/17, paras. 35.

[100] CJEU Judgment of the Court (Grand Chamber) of 2 May 2006, United Kingdom of Great Britain and Northern Ireland v European Parliament and Council of the European Union, Case C-217/04, paras. 62-63.

landscape by introducing cybersecurity requirements for products with digital elements and avoid overlapping requirements stemming from different pieces of legislation. A horizontal regulatory intervention on cybersecurity of products would do away with legal uncertainty on these aspects triggered by a patched approach taken in various product-specific or general product-related pieces of legislation. It would create greater legal certainty for operators and users across the Union, as well as a harmonisation of the European single market, creating more viable conditions for operators aiming at entering the EU market.

3.2. Subsidiarity: Necessity of EU action

The strong cross-border nature of cybersecurity in general and the growing risks and incidents, which have spill-over effects across borders, sectors and products, mean that the objectives of the present intervention cannot effectively be achieved by Member States alone. Taking into account the global nature of markets for products with digital elements, Member States face the same risks with respect to the same product with digital elements on their territory. For example, a recent study on infected IoT products across the internal market has revealed that it is the same nine manufacturers in each country that are responsible for placing the highest number of IoT devices on the market that have been infected as a result of vulnerabilities, concluding that "international collaboration among regulators in various countries is a feasible path. This would not only bundle scarce resources on the side of governments, but is also more likely to influence manufacturer behaviour through collective action. An obvious starting point would be coordination at the level of the European Union."[101]

An emerging patchy framework of potentially diverging national rules also risks hampering an open and competitive single market for products with digital elements. Some Member States, such as Germany and Finland have already taken first (non-binding) measures to improve the security of products with digital elements (see *section 6.3*). National approaches in addressing the problems, and in particular approaches introducing mandatory requirements, will only create additional legal uncertainty and legal barriers. Companies could be prevented from seamlessly expanding into other Member States, depriving users of the benefits of their products.

Given the lack of negotiation power of individual users on a global products market with large multinational manufacturers (see *section 2.2.5*), regulation at national level would not be effective. In a 2021 report, the Dutch Safety Board concluded that the products with digital elements market "can hardly be influenced by users in the Netherlands alone. Influencing such a global market requires a larger power block, for example at EU or UN level, or based on joint actions by end users."

Joint action at EU level is therefore necessary to establish a high level of trust among users, increasing the attractiveness of EU products with digital elements. It would also benefit the (digital) single market and internal market in general by providing legal certainty and achieving a level playing field for manufacturers of products with digital elements. Ultimately, as referred to in *section 1,* the Council Conclusions of 23 May 2022 on the development of the European Union's cyber posture[102] call upon the Commission to propose, by the end of 2022, common cybersecurity requirements for connected devices.

3.3. Subsidiarity: Added value of EU action

The objectives of the initiative can be better achieved at Union level so as to avoid a further fragmentation of the single market into potentially contradictory national frameworks. A single framework regarding cybersecurity requirements for products with digital elements would provide legal certainty and avoid overlapping or contradictory requirements stemming from different

[101] Rodríguez et al (2021): "Superspreaders: Quantifying the Role of IoT Manufacturers in Device Infections", *20th Annual Workshop on the Economics of Information Security (WEIS 2021)*, for a more detailed discussion of IoT consumer device security, p. 8

[102] Council conclusions on the development of the European Union's cyber posture (2022).

pieces of legislation. Harmonised EU requirements would facilitate compliance for manufacturers of products with digital elements and create more viable conditions for operators aiming at entering the EU market.

Users' trust that products with digital elements acquired in any Member State comply with a harmonised set of requirements would increase their trust in and demand for these products. Given the global and cross-border nature of the digital market and the internet, the intervention would reduce negative cross-border spill-overs and costs to society linked to mitigating risks of non-secure products.

As regards the **proportionality** of the intervention, the measures in the policy options considered would not go beyond what is needed to achieve the general and specific objectives and would not impose disproportionate costs. More specifically, the intervention considered would ensure that products with digital elements would be secured throughout their whole life cycle and proportionally to the risks faced through objective-oriented and technology neutral requirements that remain reasonable and generally corresponding to the interest of the entities involved.

4. Objectives: What is to be achieved?

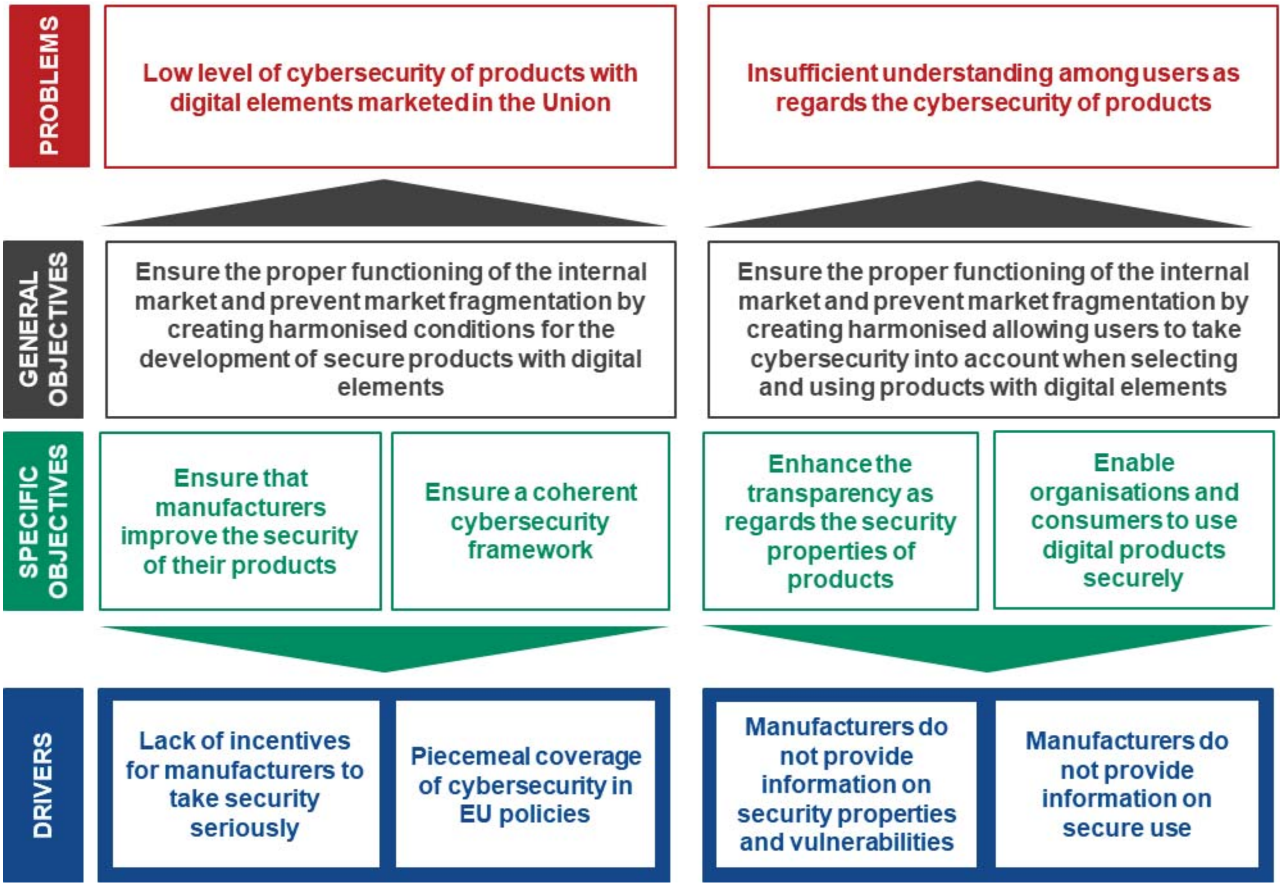
PROBLEMS
Low level of cybersecurity of products with digital elements marketed in the Union
Insufficient understanding among users as regards the cybersecurity of products
GENERAL OBJECTIVES
Ensure the proper functioning of the internal market and prevent market fragmentation by creating harmonised conditions for the development of secure products with digital elements
Ensure the proper functioning of the internal market and prevent market fragmentation by creating harmonised allowing users to take cybersecurity into account when selecting and using products with digital elements
SPECIFIC OBJECTIVES
Ensure that manufacturers improve the security of their products
Ensure a coherent cybersecurity framework
Enhance the transparency as regards the security properties of products
Enable organisations and consumers to use digital products securely
DRIVERS
Lack of incentives for manufacturers to take security seriously
Piecemeal coverage of cybersecurity in EU policies
Manufacturers do not provide information on security properties and vulnerabilities
Manufacturers do not provide information on secure use

Figure 2: Intervention logic

4.1. General objectives

Based on the main problems identified in the *section 2.1*, the main objectives of the intervention should be as follows:

General Objective 1 (GO1): Ensure the proper functioning of the internal market and prevent market fragmentation by creating harmonised conditions for the development of secure products with digital elements.

The intervention should ensure that hardware and software products are released to the market with fewer vulnerabilities and that manufactures take the security seriously throughout a product's entire life cycle, in particular by providing timely security updates. In addition, it is important that manufacturers prevent malicious actors from tampering with production code.

General Objective 2 (GO2): Ensure the proper functioning of the internal market and prevent market fragmentation by creating harmonised allowing users to take cybersecurity into account when selecting and using products with digital elements.

The intervention should ensure that both consumers as well as business users and other organisations are able to select products whose security properties match their security requirements. In addition, measures should be taken to support users in operating technical in a secure manner.

4.2. Specific objectives

Based on the problem drivers identified in *section 2.2* and with a view to reaching the two general objectives defined above, the specific objectives of the intervention should be as follows:

To address the problem of low level of cybersecurity of products with digital elements marketed in the Union:

SPO1 Ensure that manufacturers improve the security of their products with digital elements since the design and development phase and throughout the whole life cycle of those products

SPO2 Ensure a coherent cybersecurity framework, facilitating compliance for hardware and software manufacturers

To address the problem of insufficient understanding among users as regards the cybersecurity of products:

SPO3 Enhance the transparency as regards the security properties of products with digital elements

SPO4 Enable organisations and consumers to use products with digital elements securely

As referred to in *section 2.2.5,* there are certain additional problem drivers that will not be addressed by the proposed intervention. This is not to say that the intervention will have no impact at all on these drivers (see *section 6.7*).

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section presents the policy options, including the baseline scenario, that have been considered for addressing the problems identified in *section 2* and meeting the objectives set out in *section 4.*

Problem drivers	**Specific policy objectives**					**Policy options**			
		PO1 (soft law)	**PO2** (ad-hoc interv.)	**PO3** (mixed appr.)		**PO4** (horiz. interv.)			
						PO4 a) (horiz. interv. only critical software)		**PO4 b)** (horiz. interv. all software)	
				PO 3 i)	**PO 3 ii)**	**PO 4 a) i)**	**PO 4 a) ii)**	**PO4 b) i)**	**PO4 b) ii)**
DR1: Lack of incentives for manufacturers to take security seriously	**SPO1:** Ensure that manufacturers improve the security of their products with digital elements since the design and development phase and throughout the whole life cycle of those products	—Communications, guidance and recommendations for supply side stakeholders, including on non-embedded software —Recommendation on public procurement of products with digital elements — Development of additional European cybersecurity certification schemes	—Amendments to *existing* product specific legislation —Integrate cybersecurity into *future* product-specific NLF legislation	—Horizontal regulatory intervention for tangible products with digital elements (excluding non-embedded software) —A potential legal act on non-embedded software at a later stage (staggered approach)		—Horizontal regulatory intervention for a broad scope of **tangible and only critical intangible products** with digital elements (including non-embedded software)		—Horizontal regulatory intervention for a broad scope of **tangible and intangible products** with digital elements (including non-embedded software)	
				— self-assessment by default for all products covered	— third-party assessment for a narrow share of critical tangible products	— self-assessment by default for all products covered	— third-party assessment for a narrow share of critical tangible and intangible products	— self-assessment by default for all products	— third-party assessment for a narrow share of critical tangible and intangible products
DR2: Piecemeal coverage of cybersecurity in EU policies	**SPO2:** Ensure a coherent cybersecurity framework								
DR3: Manufacturers do not provide information on security properties and vulnerabilities	**SPO3:** Enhance the transparency as regards the security properties of products with digital elements	*(partly included in the measures addressing DR1)*	*(partly included in the measures addressing DR1)*	Horizontal intervention to include transparency requirements for tangible products with digital elements on security properties		Horizontal intervention to include transparency requirements for both tangible and critical intangible products with digital elements on security properties		Horizontal intervention to include transparency requirements for both tangible and intangible products with digital elements on security properties	

DR4: **M**anufacturers do not provide information on secure use	**SPO4:** Enable organisations and consumers to use products with digital elements securely	*(partly included in the measures addressing DR1)*	*(partly included in the measures addressing DR1)*	Horizontal intervention to include transparency for tangible products with digital elements requirements on secure use		Horizontal intervention to include transparency requirements for both tangible and critical intangible products with digital elements on secure use	Horizontal intervention to include transparency requirements for both tangible and intangible products with digital elements on secure use

Table 1: Problem drivers, specific objectives and policy options

5.1. What is the baseline from which options are assessed?

5.1.1. *The relevant EU markets*

A horizontal regulatory intervention would lay down requirements for some or all products with digital elements marketed in the Union (with the broadest scope under policy option 4). Requirements would not only cover the final product with digital elements (e.g. a smart phone), but also their components, both for hardware and software. As a result, depending on the policy options, the initiative would have an impact throughout the entire digital supply chain, and provide users with a very high level of assurance regarding the security of products. *See also the illustrative example of smart phones in the description of options 3 and 4, section 5.2.*

The relevant markets include software and hardware products, which the policy options will impact to a different extent. Due to the absence of a consistent and comparable publicly available dataset on the dimension of the market for products with digital elements, certain proxy indicators have been used to assess the value of the relevant markets. The methodology and the market analysis is described in more detail in *Annex 3*. The analysis includes the value produced by both non-EU and EU companies in the EU market, while it was not possible to generate aggregated values for each of these two.

5.1.1.1. *Software market*

Based on the data gathered by a recent study which provided for a breakdown of the software and software-based services market,[103] the following categories can be identified: *(1) Software products;[104] (2) Software-related services;[105] (3) Cloud computing;[106] (4) Games.* The present analysis is focused on software products (including games) and does not explore the specific markets related to software services and cloud. This is because the latter would not be included in the scope of a potential horizontal regulation (policy options 3 and 4), since only products (and hence software as a product) would be included in the scope and not services.[107]

The proxy indicator used to assess the dimension of the software market is based on a subset of NACE 2 activities of the Information and Communication sector (see *Annex 3*).

The proxy indicates that, in 2019, the **production value** of the EU-27 software development amounted to over **EUR 236 billion**.[108] During the same year, the sector recorded a **turnover** of EUR 265 billion with a total **number of enterprises** of 365 759.[109]

In terms of **number of companies,** the software industry is almost entirely composed of **SMEs**. Whereas the total number of enterprises for the selected sample amounted to 341 781 in 2019, the number of SMEs operating in the software market in the same year reached 340 918, accounting for 99.7 % of the total.[110] However, when looking at the **turnover generated by SMEs** in the software market for sample countries, it **accounts for 41 %** of the EUR 305 444 billion which

[103] https://op.europa.eu/en/publication-detail/-/publication/480eff53-0495-11e7-8a35-01aa75ed71a1

[104] including infrastructure software & platforms, application software products; excluding SaaS.

[105] including application-related project services, application management, application hosting, infrastructure-related project services, infrastructure outsourcing; excluding cloud services.

[106] paid web-based services consisting of IaaS, PaaS, SaaS.

[107] Furthermore, software products not sold on the market, i.e. in-house software development (i.e. resulting in products that are not distributed externally as software products), were not included in the analysis.

[108] This data appears to be consistent with other estimations. For instance, the software development market which includes writing, modifying and supporting computer code, databases and webpages is estimated to amount to 255 billion. https://www.ibisworld.com/eu/industry/software-development/3595/

[109] EUROSTAT. Annual detailed enterprise statistics for services. The data is under evaluated due to the data for some countries due to confidentiality. The data for Estonia, Ireland, the Netherlands and Slovakia is missing for one of the NACE 2 indicators.

[110] 94 % of SMEs operating in the software market are micro enterprises (less than nine employee).

shows the **important relative weight of big market players** that may constitute only 0.3 % of enterprises in the market but generate 59 % of revenue.

When referring to turnover, it is difficult to assess the share of the **revenues related to B2C and B2B**. Nevertheless, by looking at the German software market, it is possible to highlight that those revenues from software sales **rely heavily on B2B with 67.9 %** of revenue being driven from business. This split shows a high integration of the software market with other economic sectors that rely on software for their operations.[111]

The size of **embedded software** is valued at EUR 2.4 billion in 2020 and is expected to continue growing at a compound annual growth rate (CAGR) of 5.5 % from 2021 to 2027. **Non-embedded software** represents the **biggest part of the industry's sales**.[112]

Globally, the revenue in the software market[113] is projected to reach **USD 608.70 billion in 2022**, with nearly half of the revenue generated[114] in the United States. Most competitive software companies are from the United States followed by Asia. According to McKinsey, in 2020, there was no European company on the list of the world's ten most valuable software and software-enabled companies, and were only three among the top 20. Furthermore, over a third of the 100 most valuable companies in the United States came from the software sector, as did about a quarter of those in Asia. In Europe, that figure stood at just 7 %.[115]

5.1.1.2. Hardware market

To estimate the value of the hardware market, several proxies were explored based on Eurostat data in the study accompanying the impact assessment: the **ICT manufacturing sector – standard classification** (ICT-SC)[116] and the **extended classification** (ICT-EXT-ADJ). The latter covers more manufacturing sectors than those which are 'purely' digital. The estimates based only on the ICT manufacturing sector are under the real values of all products with digital elements placed on the Union market. At the same time, the estimates based on the extended classification are likely over the real value: The adjustment indicators used to estimate the weight of products with digital elements as compared to non-products with digital elements within the same category are an overestimation, since the proxy used for this adjustment considered the digital intensity of the manufacturing sub-sectors, which does not necessarily match the production of digital goods[117] (*see Annex 3*).

In 2019, the **production value** of the EU-27 ICT-SC amounted to **EUR 222 billion**. During the same year, the sector recorded a **turnover** of EUR 285 billion[118] with a total **number of enterprises** of 22 773.[119]

When considering the ICT-EXT-ADJ indicator, the production value of the EU-27 amounted to EUR 1 081 billion, the turnover to EUR 1 220 billion and the total number of enterprises of 249 513 in 2019. *As mentioned above, this would most likely be an overestimation.*

[111] Deloitte (2019). The German Technology Sector. From Hardware to Software & Services, p. 12.

[112] https://www.graphicalresearch.com/industry-insights/1988/europe-embedded-software-market

[113] including on-premise and cloud-enabled software.

[114] USD 303.10 billion in 2022.

[115] https://www.mckinsey.com/industries/technology-media-and-telecommunications/our-insights/reversal-of-fortune-how-european-software-can-play-to-its-strengths

[116] Deloitte (2019), p. 7, but also Barefoot, K.; Curtis, D.; Jolliff, W.; Nicholson J.R.; Omohundro, R.; (2018). Defining and Measuring the Digital Economy – Working Paper. Bureau of Economic Analysis – US Department of Commerce. p. 47.

[117] For example, there can be businesses with high digital intensity that do not produce product with digital elementss.

[118] This data appears to be consistent with other estimations. For instance, Research and Markets assess the IT Hardware Market in Europe at USD 228.9 billion in 2020. The IT hardware market includes all physical components integral to computing such as computing, networking, security and server hardware. More info available at: https://www.researchandmarkets.com/reports/5350389/it-hardware-in-europe-market-summary

[119] Eurostat: Annual enterprise statistics for special aggregates of activities (NACE Rev. 2). [SBS_NA_SCA_R2]

The European ICT-SC manufacturing industry is almost entirely composed of SMEs. Whereas the total number of enterprises amounted to 22 773 in 2019, the **number of SMEs operating in the hardware market in the same year reached 22 119, accounting for 97.13 %** of the total.[120] However, when looking at the turnover generated by SMEs in the hardware market, it accounts for 21.9 % of the global turnover which shows the very important weight of larger companies that may constitute only 2.87 % of enterprises in the market but generate 78.1 % of revenue.

The **weight of the ICT manufacturing** on the overall European economy was stable over the past five years and still appears to be limited, amounting to 0.41 % in 2019.[121]

When referring to turnover, it is difficult to assess the share of the **revenues related to B2C and B2B**. Nevertheless, by looking at the German hardware market, it is possible to highlight that revenues from hardware sales were equally split between the B2B (48.1 %) and B2C (51.9 %) sectors in 2018. The reason behind this split is **the strong consumer business stream** connected to the sale of smartphones, laptops and general consumer electronics. This represents an important distinction with the software and services market where the B2B component appears to be predominant, accounting for more than two-thirds of the overall sales.[122]

5.1.1.3. Total market value

The global market for products with digital elements encompassing software and hardware has a total production value in Europe of EUR 458 billion and turnover of EUR 550 billion in 2019,[123] if the hardware market is considered as only including the elements of the ICT-SC indicator. The number of enterprises operating in this sector is **388 532,** when considering the limited scope of ICT-SC, with a vast majority being SMEs (99.58%).

Considering the extended classification (ICT-EXT-ADJ), these values are up to EUR 1317 billion in production value and EUR 1485 billion in turnover for 2019. The number of enterprises in this sector is **615 272**, with a vast majority being SMEs (99.58%). These estimates however may be overestimated since they rely on proxies of digital intensity and not production of digital goods per se.

Based on this data, under both indicators, SMEs account for about 34.4 % of the turnover generated in the market for products with digital elements for 2019. Aggregated indicators for the global market for products with digital elements in 2019 can be found in *Annex 3*.

5.1.2. Baseline scenario

The baseline scenario entails no common (i.e. horizontal) legislation to set cybersecurity requirements for products with digital elements.

As referred to in *sections 1 and 2.2.2.,* the current **EU framework applicable to products** comprises several pieces of legislation that cover only certain aspects linked to the cybersecurity of tangible products with digital elements and, where applicable, embedded software concerning these products. This legislative framework **was not conceived to tackle specifically the challenges linked to cybersecurity of products with digital elements**. It largely covers requirements for placing the products on the market, but not necessarily for the whole life cycle of products, which is crucial in the case of products with digital elements. The current legislation also fails to cover a variety of widely used hardware[124]. Moreover, **non-embedded software** is not currently addressed despite the major impact resulting from insecure non-embedded software. for a detailed gap analysis, see *Annex 13*.

[120] Source: EUROSTAT [SBS_SC_IND_R2]

[121] EUROSTAT. Percentage of the ICT sector on GDP. [TIN00074]. 82 % of SMEs operating in hardware market are micro enterprises (less than nine employee).

[122] Deloitte (2019). The German Technology Sector. From Hardware to Software & Services, p. 12.

[123] Second Interim Study Report N° 2019-0024 supporting the impact assessment.

[124] e.g. hardware not falling under the RED, such as wired-only hardware.

As a significant first step towards increasing the level of cybersecurity of wireless devices, the **delegated act under RED**,[125] adopted in October 2021, aims to improve the cybersecurity of these devices on the European market by laying down new general requirements which manufacturers will have to follow in the design and production of the concerned products, constitutes. Non-embedded software is however not covered by these requirements. Furthermore, the act does not provide for duty of care for the whole life cycle of these products.

It can be assumed that, given the pace, spread and importance of digitization for all sectors of economy, any new product-related legislation in the NLF would include certain cybersecurity-related aspects. However, these would be product- and/or sector-specific and therefore would not be able to address cybersecurity risks in a targeted and comprehensive way. Leaving the integration of cybersecurity-related requirements only for certain product legislation would leave other categories of products not covered by such measures and possibly raise the risk of different and even diverging requirements stemming from separate pieces of legislation. This would lead to a **fragmented regulatory landscape, potential discrimination and legal uncertainty**, affecting the well-functioning of the internal market.

Maintaining this status quo would therefore mean that cybersecurity would remain only partially addressed in product-related legislation, while existing horizontal cybersecurity legislation, such as the NIS framework or the Cybersecurity Act, would not provide for the means to establish cybersecurity requirements for products with digital elements.

In the scenario of maintaining the status quo, the development of **European voluntary cybersecurity certifications schemes** would continue as foreseen, based on the Cybersecurity Act, implying a **voluntary conformity assessment**[126]. Manufacturers do not have a legal obligation to seek certification for their products. The proposal for the NIS2 Directive expected to enter into force before the end of 2022, with a transposition period of 21 months, provides for an empowerment for the Commission to adopt delegated acts specifying categories of essential entities shall be required to obtain a certificate under a European certification scheme. However, this would rather cover a limited category of products used in particular sectors and would therefore not be sufficient to address systematic cybersecurity-related issues of all products with digital elements, as described in *section 2*.

Other voluntary national practices and measures would continue, such as **voluntary labelling** measures of certain categories of products, as it is currently the case in few Member States. This can raise the risk of further fragmenting the internal market.

Finally, maintaining the status quo would entail no specific soft law or regulation at EU level as regards cybersecurity of **standalone software.**

At **national level**, Member States may develop targeted initiatives within the boundaries of European law to better protect their consumers. For example, Member States could put in place diverging security and transparency obligations for operating systems or virtual private network software, which is becoming increasingly popular since the beginning of pandemic.

In absence of harmonised rules, users, such as critical infrastructures obligated under the revised NIS Directive to take their supply chain security more seriously, may start putting in place diverging contractual requirements for manufacturers of products with digital elements.

At **global level**, it can be assumed that the security of supply chain measures taken recently, in particular in the United States of America (notably mandatory measures for critical software under

[125] C(2021) 7672 final supplementing RED, with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of RED.

[126] There are currently three certification schemes at various stages of development under the European Cybersecurity Certification Framework on the basis of the Cybersecurity Act: (i) common criteria which concerns predominantly high assurance for components (smart cards, hardware security modules) used as a 'root of trust' or 'secure elements' for applications in passports, digital identity cards, smart meters, tachographs, smart phones, trusted platform modules etc (ii) cloud services; (iii) 5G.

public procurement) and the UK (notably security requirements of consumer IoT), as well as potentially further similar measures, would influence the playing field for European manufacturers present on global markets, potentially putting them at a disadvantage. A horizontal European regulation in this regard would be the most comprehensive to be introduced world-wide, creating legal certainty and getting Europe to set the path forward for cybersecurity in products with digital elements at global level.

As described in *section 2.4*, some problem drivers may diminish in the future. The labour market may for example provide more qualified security professionals, either as a result of market forces or due to government intervention. Awareness raising campaigns and adapted school curricula may also lead to users become more aware of cybersecurity risks and more proficient in using producta with digital elements securely. Additional international standards on products and processes may also emerge, helping manufacturers improve the design and development of products with digital elements.

5.2. Description of the policy options

The policy options analysed range from the least interventionist and closer to the baseline scenario (option 1 – soft law approach and voluntary measures), through a lighter option that could entail certain legislative interventions on a case-by-case basis (option 2 – ad-hoc regulatory intervention), up to the most interventionist (options 3 and 4 – horizontal regulation on cybersecurity), with option 4 varying in relation to scope (option 4 b) having the most comprehensive scope, all products with digital elements, covering also non-embedded software). Both policy options 3 and 4 also vary in relation to the level of conformity assessment (with and without mandatory third-party assessment). Furthermore, the various options analysed took account of the extent to which various measures, vertical or horizontal, or combination thereof could address the type of cybersecurity risks the products with digital elements are exposed to and the problems identified and their drivers.

Policy options 3 and 4 are based on the New Legislative Framework (NLF). The NLF places obligations on manufacturers and their authorised representatives as well as on importers and distributors. A detailed description of the NLF can be found in *Annex 11*. The NLF is primarily a framework placing obligations on economic operators, as the aforementioned types of entities. As a result, it is not foreseen to place obligations on users, such as consumers as well as companies or other types of organisations.

Departing from the status quo, the following options are therefore considered in view of the specific objectives to be achieved as set out in *section 4.2* above.

Option 1: Soft law approach and voluntary measures

In this option, there would be no mandatory regulatory intervention. Instead, the Commission would issue **communications, guidance, recommendations** and potentially **codes of conduct** to encourage **voluntary measures (self regulation)**, **including potentially on non-embedded software**, and **provide guidance** to support supply-side stakeholders to enhance the digital security of their products. These guidelines or recommendations could consider the elements that are referred to in options 3 and 4 below under the potential cybersecurity requirements. Such recommendations or guidelines could also be limited only to the **public procurement** of products with digital elements,[127] given existing practices of public procurement which oftentimes include security-related considerations, such as due diligence in respect of cybersecurity when procuring certain products with digital elements in certain sectors or by certain agencies. Recommendations

[127] This is an approach taken, for example, by the US with regard to certain categories of products.

for public procurement may also ultimately have broader effects beyond strictly the public procurement framework and be also considered in private procurement a good practices.

At the same time, it would be expected for the Union Rolling Work Programme for European cybersecurity certification,[128] on the basis of Article 47(5) of the Cybersecurity Act, to consider the development of **additional European cybersecurity certification schemes** that would cover more categories of products for which cybersecurity is currently not being properly addressed, such as industrial IoT. These schemes would remain voluntary, unless otherwise decided via a delegated act for particular categories of products used in particular sectors through the empowerment provided to the Commission on the basis of the NIS2 Directive,[129] once it enters into force.

National schemes (e.g. labelling), voluntary or mandatory, would continue to be developed to compensate for the lack of EU horizontal rules.

Option 2: Ad-hoc regulatory intervention for cybersecurity of tangible products with digital elements and respective embedded software

This option would entail an ad-hoc product-specific regulatory intervention that would be limited to adding and/or amending the cybersecurity requirements in the already existing legislation or introducing new legislation as new risks emerge, including potentially on non-embedded software. A number of legislative initiatives or reviews are currently being prepared or negotiated with a view to integrate more broadly digitization and the development of new technologies, with a tendency to cover certain cybersecurity aspects, either through a safety angle (see the general product safety framework) or more specifically to certain technologies or products (e.g. AI). A scenario where this approach would be continued, in the absence of a horizontal intervention, can therefore be considered realistic.

More specifically,

i. **For existing NLF legislation**,**[130]** it would entail:

- case-by-case analyses that may lead to legislative amendments (*gradually or at once*) in relation to those products that have a digital element, but for which the existing legislation does not foresee any cybersecurity requirements.
- based on a case-by-case analysis, consider amendments to legislation already containing certain cybersecurity requirements, to the extent necessary, to include more specific or targeted cybersecurity requirements, including where applicable in relation to embedded software. This could a possible amendment of the RED Directive in order to equally extend the scope of the RED delegated act and to include non-embedded software as well as a duty of care obligation for the whole life cycle of the product.

ii. **For future NLF legislation**, it would entail:

- cybersecurity requirements to be introduced when new product (NLF) legislation is developed and cybersecurity relevant.

iii. **For 'old approach' product legislation**,**[131]** it would entail:

[128] Programme which aim is to identify strategic priorities for future European cybersecurity certification schemes, as provided for by Article 47 of the Cybersecurity Act. The programme shall in particular include a list of ICT products, ICT services and ICT processes or categories thereof that are capable of benefiting from being included in the scope of a European cybersecurity certification scheme.

[129] Article 21 of the NIS2 proposal.

[130] For more details relating to NLF legislation, see the explanations below under this section and *Annex 11*.

[131] In the context of EU sector specific safety legislation, so-called old and new approaches are traditionally distinguished. The 'Old Approach' refers to the very initial phase of EU regulation on products, whose main feature was the inclusion of detailed

- ➢ Where necessary and where the basic acts allows, introducing amendments, in particular for empowerments on complementing or further specifying cybersecurity requirements via delegated or implementing acts.

***Note:** The **next two options (3 and 4)** entail a horizontal regulatory intervention varying in scope, largely following the **NLF approach**. This framework typically sets **essential requirements** as a condition for the placement of certain products on the internal market. These requirements are objective-oriented, followed at a later stage by harmonised standards developed by standardisation bodies, which elaborate on the technical means through which the requirements could be met. More information on standards can be found in Annex 14.*

*NLF legislation also typically provides for **conformity assessment**, which is the process conducted by the manufacturer to demonstrate whether the essential requirements relating to a product or process have been fulfilled. Conformity assessment procedures are composed of conformity assessment modules defined by the NLF, ranging from self-assessment by the manufacturer up to the assessment in certain circumstances, or in consideration of certain risks, by independent third parties. The latter are known generally as conformity assessment bodies, or more formally as 'notified bodies'. Member States have the responsibility to decide which of their conformity assessment bodies fulfil the necessary criteria to become notified. This may happen through an accreditation process. Accreditation is a formal system which provides an independent attestation of the competence, impartiality and integrity of conformity assessment bodies. The NLF framework also typically provides for EU **market surveillance**, which is under the responsibility of the Member States. For more details, see Annex 11.*

Option 3: Mixed approach, including horizontal mandatory rules for cybersecurity of tangible products with digital elements and respective embedded software and a staggered approach for non-embedded software

This option would entail a **regulation introducing horizontal cybersecurity requirements for all tangible products with digital elements and the software embedded** within these, as a condition for placement on the market. Non-embedded software would not be regulated. Given its relatively broad scope and since the policy option proposes both security requirements as well as transparency requirements, policy option 3 addresses all four problem drivers as far as hardware products and their embedded software is concerned. Obligations would apply to manufacturers and to a lesser extent to also to distributors (such as online shops or brick and mortar stores) as well as to importers. The main building blocks of the regulatory intervention under this option would be as follows:

a) Scope:

- **all tangible products with digital elements, i.e. hardware** (e.g. *end devices* such as: laptops, smartphones, sensors and cameras; smart robots; smart cards; smart meters; mobile devices; smart speakers or *networks,* such as: routers; switches)
- the respective **embedded software associated with these products**, meaning firmware or other software that is essential for the function of the end-product (e.g. operating systems; network system; storage and security management, etc.).

It will not cover non-embedded software, meaning software that is additional to the function of the device on which it is downloaded (e.g. extended operating system, mobile apps). Instead, a

technical requirements in the body of the legislation. Certain sectors such as food or transport are still being regulated on the basis of 'old approach' legislations with detailed product requirements. The so-called 'New Approach' was developed in 1985, whose main objective was to restrict the content of legislation to 'essential (high-level) requirements' leaving the technical details to European harmonised standards. On the basis of the New Approach, the New Legislative Framework (NLF) was then developed in 2008, introducing harmonised elements for conformity assessment, accreditation of conformity assessment bodies and market surveillance. Today more than 20 sectors are regulated at EU level based on the NLF approach, e.g. medical devices, toys, radio-equipment or electrical appliances.

staggered approach would be considered**,** with **soft law** measures such as guidelines or recommendations taken as a first step, potentially followed by horizontal regulatory intervention, depending on the results of implementing such measures. The reason is that traditionally non-embedded software is not covered by existing product legislation within the NLF and therefore an intermediary period could be considered via soft law measures to test the potential uptake by the relevant software manufacturers.

The rationale of analysing an option not covering non-embedded software in the scope is as follows: (i) it corresponds to the current NLF legislation, which covers as a rule tangible products and at most their embedded software and (ii) it is an option suggested by certain stakeholders on the grounds that more judicious consideration is necessary before imposing cybersecurity requirements on non-embedded software due to its intangible nature.

The definition of "product with digital elements" would specify that "products with digital elements" refer to both hardware and software as well as hardware and software components placed on the market separately.

b) Requirements and obligations:

In terms of **cybersecurity requirements and obligations for economic operators**, it would mandate that tangible products with digital elements and their embedded software shall only be made available on the market if, where dully supplied, properly installed, maintained and used for their intended purpose or under conditions which can be reasonably foreseen, they meet the specific cybersecurity requirements. While manufacturers would be required to comply with the requirements, they would not be held accountable for how the product will be used.

Nature of the requirements: These requirements would be **objective-oriented, technology-neutral and future proof** against a fast-evolving product and technology landscape. They would not be sector or product-specific. In terms of granularity, they would not be too prescriptive as they would be applicable to a wide category of products, yet more specific than a very generic principle that would only require that products are cyber secure or protected.

Content of the requirements**:** The requirements would **mandate** manufacturers to factor in **cybersecurity in the design and development** of the products with digital elements, to exercise **due diligence** on security aspects when designing and developing their products, to be **transparent** on cybersecurity aspects that need to be made known to customers and to ensure security **support (updates)** in a proportionate way.

More specifically, manufacturers would mainly be mandated to:

- Design and develop these products in consideration of the risk posed to the security of network and information systems.
- Design and develop these products in such a way that they provide **adequate resilience against security threats,** ensure that the products can be **used securely** and ensure protection of stored, transmitted or otherwise processed **data** and that security is taken into account, as applicable, **in all phases** of the **design, development and production process**.
- Put in place design and development solutions for the product, i.e. **security by design and by default** mechanisms[132], to deliver with a secure by default configuration; capabilities to perform or support integrity checks; authentication and access control mechanisms;guarantees for protection of the exposed attack surfaces; protection against degradation or denial of service attacks; ways for enabling adequate security updates and ensure that adequate security support can be received.
- In addition to the product-related security requirements described above, have in place **vulnerability management, vulnerability disclosure policies and testing**.

[132]

- In addition, to ensure the effective functioning and security of the internal market and awareness of cybersecurity risks by relevant authorities and bodies, manufacturers should **report vulnerabilities** that are being actively exploited and any incident having an impact on the cybersecurity of these products to the EU agency for cybersecurity, ENISA. Based on the received information, ENISA should prepare intelligence on emerging trends regarding cybersecurity risks in products with digital elements to the national competent authorities and the European Commission, e.g. in the NIS Cooperation Group, as well as provide advice to support the implementation process of this Regulation.

These requirements derive from the overall objective of ensuring a high level of cybersecurity of products with digital elements. They take account of well-settled practices in terms of cybersecurity of products, factoring in the security objectives that the Cybersecurity Act establishes, as well as existing international standards for certain specific products[133], such as the ETSI standards for IoT consumer products.[134]

The above-mentioned requirements are inter-dependent and complementary to each other, ensuring as a whole that the respective product would be secure. For example, for certain risks and intended use cases it may be appropriate to integrate an authentication mechanism into a device to prevent unauthorised access and data theft (requirement "*protection from unauthorised access by appropriate control mechanisms*"). For this requirement to be effective, it is essential that other requirements are fulfilled as well: for instance, if the device is shipped with a widely-known default password, a malicious actor could access the data despite an adequate authentication mechanism being in place. The device should therefore not be shipped with any default password, but instead require users to select a strong custom password upon first use (requirement *"delivered with a secure by default configuration").*

In addition to the above-mentioned requirements concerning the products as such, obligations would be set up for economic operators, starting from manufacturers, up to distributors and importers, in relation to the placement on the market of the tangible products with digital elements and their embedded software, as adequate for their role and **responsibilities on the supply chain**. These obligations would mainly be:

- **Transparency-related**, including in terms of information made available to end users, keeping records or disclosure of information concerning the components of a product, ensuring **duty of care**, **vulnerability disclosure.**
- Making available **technical documentation**.
- Providing **information and guidance** to users on cybersecurity aspects.

Who should respect these obligations? When placing any product with digital elements on the market, manufacturers would be required to ensure that it has been designed, developed and produced in accordance with the essential cybersecurity requirements set out by the regulation. This would apply no matter whether the product is for end users or embedded in a final product. For tangible products with digital elements and software embedded in such products that is essential for the functions of these products, the responsibility for the compliance with the essential cybersecurity requirements would pertain to the manufacturer of the whole product.

The essential cybersecurity requirements would be followed by a **standardisation mandate** for the standardisation bodies to develop harmonised standards which would set out the technical specifications, some product or sector-specific, by which compliance with the requirements could be ensured.

[133] Such as IEC 62443 series

[134] ETSI: "Consumer IoT security".

The regulation setting out the horizontal requirements would not provide for liability rules. These are set out by the general EU product liability framework[135] (currently under review) which sets out liability rules for defective products so that consumers can claim compensation for damage caused by defective products. The Product Liability Directive establishes the principle that the manufacturer of a product is liable for damages caused by a defect in their product irrespective of fault ("strict liability"). It defines the conditions that allow injured parties to seek redress from injuries or damage to personal property caused by defective products marketed within the EU.

c) Whole life cycle:

As regards market placement coverage, the whole life cycle of the products with digital elements would be considered, and in particular obligations for manufacturers to provide **information** about the **end-of-life** of the products and **the security support provided,** as well as obligations to provide **security updates** and support for a **reasonable period of time** (e.g. average of five years), while ensuring proportionality.

This approach would be compatible with the EU **framework on liability for defective products**, now undergoing review, which, among others, aims to take into account the dynamics and seriousness of cybersecurity threats and which is expected to introduce liability for situations when damages are triggered by vulnerabilities. The liability of an economic operator may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person [including, for example, rejecting a software security update] or any person for whom the injured person is responsible.

In the absence of corresponding horizontal regulation setting out post-market placement security obligations on manufacturers, the leverage of the future product liability framework (currently under review) on the manufactures who may be held liable for damages caused by lack of cybersecurity measures would be more limited. For example, absent specific cybersecurity requirements that manufacturers must comply with in relation to their products with digital elements, there will be more limited ways to successfully trigger liability for damages caused by cybersecurity-related defects of such products.

d) Conformity assessment:

Different **sub-options** may be considered with regard to the **conformity assessment procedures**:

- **Sub-option 3 i)** No risk categorisation and self-assessment of conformity by manufacturer only, while manufacturers may voluntarily opt for a third-party conformity assessment when deemed appropriate.
- **Sub-option 3 ii)** Two risk categories:
  - ➢ by default: self-assessment, and
  - ➢ critical products: third-party conformity assessment prescribed for certain categories of products under a risk-based approach. The categories would be explicitly listed in the horizontal regulation, with the possibility to be updated based on a delegated act empowerment and could include, for example, products such as critical software, products that serve as safety components, industrial IoT and industrial control systems. They would take account of factors such as intended use or functionality :
    - ✓ *based on cybersecurity functionality,* software products that have *security-critical functions* or pose similar significant potential for harm if compromised;[136]

[135] Product Liability Directive: Directive 85/374/EEC.

[136] i.e. software that has, or has direct dependencies upon, one or more components with at least one of these attributes: designed to run with elevated privilege or manage privileges; has direct or privileged access to networking or computing resources; designed

- ✓ *based on intended or reasonably foreseeable use or potential risk of physical harm:* products with digital elements intended to be used in a sensitive environment, including in critical infrastructures or in an industrial setting.

- ➢ In addition, an empowerment for delegated acts would be considered for the Commission to specify, based on established criticality criteria in the basic act, the categories of products for which certification, on the basis of EU cybersecurity certification schemes established by the Cybersecurity Act would be required. See table in *Annex 12* illustrating the two-level risk categories for the conformity assessment.

Even if not mandatory, EU cybersecurity certification schemes would also continue to be used based on the Cybersecurity Act and, where applicable, could be used as evidence to demonstrate compliance with the essential requirements. It would rather be expected however for the planned new European cybersecurity certification schemes regarding products with digital elements to be more limited in this option than in the status quo or in option 1 or 2.

Where compliance of the product with the applicable essential requirements has been demonstrated, either via self-assessment modules or by a third party, manufacturers would draw up an EU declaration of conformity and affix the CE marking.

e) Interplay with other product-related legislation (notably NLF):

The horizontal cybersecurity requirements in this option would come to complement and co-exist with existing product-related legislation.

The horizontal cybersecurity rules would establish non-product-specific essential cybersecurity requirements that would be considered a baseline for all products with digital elements. If justified by the particularities of certain products and if the horizontal rules, and the harmonised standards to be developed on this basis, would not suffice, additional product-specific requirements could still be established by dedicated legislation.[137] Furthermore, for certain specific NLF legislation, such as the proposed Machinery Regulation,[138] where certain product-specific cybersecurity requirements are already covered for safety components, the horizontal cybersecurity requirements could include provisions to stipulate that those particular requirements would take precedence.

Overall, the act setting out the horizontal cybersecurity requirements would set out a rule of *lex specialis,* specifying that where, for a certain category of products with digital elements, the cybersecurity risks addressed by the essential requirements are covered by other more specific requirements of other Union harmonisation legislation, these horizontal cybersecurity requirements shall not apply to those products to the extent that the specific Union legislation in question sufficiently covers such risks, achieving the same level of protection as the horizontal requirements. In some cases, where the Union legislation in question contains requirements adapted to the sector-specific needs, including on software and general obligations on manufacturers, covering the whole life cycle of products, as well as conformity assessment procedures, the act setting horizontal requirements could exclude those products from its scope. This could be the case for Union legislation regulating medical devices,[139] certified aeronautical

to control access to data or operational technology; performs a function critical to trust; operates outside of normal trust boundaries with privileged access.

[137] For example, as regards Electronic Health Records, the recently adopted proposal on the European Health Data Space (EHDS) will add to and complement the envisaged EU horizontal cybersecurity legislation. The EHDS will complement the horizontal legislation with product-specific requirements, adapted to the health sector specific needs (e.g. security requirements for European health records systems which provide more specific requirements specific to these systems in certain areas, such as access control).

[138] Proposal for a Regulation of the European Parliament and of the Council on machinery products, COM/2021/202 final.

[139] For example, the existing legislation on medical devices (MDR: Regulation (EU) 2017/745) contains requirements regarding devices, including on software and general obligations on manufacturers, covering the whole life cycle of products, as well as conformity assessment procedures.

equipment[140] or potentially motor vehicles.[141] Even in those cases, the horizontal requirements would still apply to certain components of those products and eventually ensure a high level of security of the supply chain.

The relationship of policy option 4 with existing vertical cybersecurity regulation. The example of cars.

UN Regulation No 155 requires manufacturers to take a number of product- and process-related cybersecurity measures that are very similar to the requirements in policy options 3 and 4. Amongst others, manufacturers must perform an exhaustive risk assessment (that considers interactions with any external systems) and protect the vehicle type against risks. Manufacturers must also put in place a Cybersecurity Management System (CSMS) covering the whole life cycle of the vehicle. The CSMS must manage dependencies that may exist with contracted suppliers, service providers or manufacturers' sub-organizations, ensuring security throughout the supply chain. Those suppliers are not directly covered by UN Regulation No 155 but would be subject to the horizontal requirements for hardware and software under policy option 4. Therefore, it will be easier for vehicle manufacturers to manage their dependencies, as the components would carry the CE marking probing compliance with cyber-security requirements.

Under UN Regulation No 155, the car manufacturer must also take measures to secure dedicated environments on the vehicle type for the storage and execution of aftermarket software (such as software media players) and perform testing to verify the effectiveness of the measures. Such aftermarket products are not covered by the UN Regulation, but would be covered by policy option 4. This would contribute to increasing the security of motor vehicles.

Of all NLF legislation, the **case of the RED Delegated Regulation** requires particular attention, because this delegated act covers three general essential cybersecurity-related requirements for a big category of tangible products with digital elements (wireless hardware products) that would be also covered by the horizontal cybersecurity requirements. More specifically, the relevant RED Delegated Regulation establishes the following three essential requirements for inter-connected radio equipment: (i) ensure network protection; (ii) ensure safeguards for the protection of personal data and privacy, (iii) ensure protection from fraud. A standardisation mandate is now being prepared, with standards likely to be developed within 2-3 years. The RED Delegated Regulation shall apply from 30 months after its entry into force.

In this option, the horizontal cybersecurity requirements would be more specific and granular than the general requirements set out in the RED Delegated Regulation for all wireless products. The RED delegated act would then be implemented until the horizontal cybersecurity requirements would start applying. From that moment, the cybersecurity requirements of the RED Delegated Regulation would become obsolete. A less optimal alternative would be to consider that compliance with the horizontal cybersecurity requirements could be presumed compliance with the cybersecurity requirements of RED delegated act.

Furthermore, when preparing the standardisation request for the horizontal cybersecurity requirements, it must be ensured that the standardisation work done with the respective RED Delegated Regulation is preserved and complemented only where needed.

See *Annex 9* for a detailed overview of the interplay with product legislation.

[140] According to Article 77 of the Regulation (EU) 2018/1139 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency (EASA), EASA is the responsible authority for the certification of relevant aviation products, parts, non-installed equipment and equipment to control unmanned aircraft remotely. The same or similar considerations would be applicable also to aerodrome equipment (Article 79) and air traffic management and air navigation services (‘ATM/ANS’) equipment (Article 80). The cyber resilience aspects of all aviation products falling under Regulation 2018/1139 are already included under the relevant technical requirements and are systematically assessed by the Agency during the certification process.

[141] The EU legislation on motor vehicles (Regulation (EU) 2019/2144, https://eur-lex.europa.eu/eli/reg/2019/2144/oj and Delegated Regulation (EU) 2022/545 supplementing Regulation 2019/2144 https://eur-lex.europa.eu/eli/reg_del/2022/545) introduces certain cybersecurity requirements, including on software updates, requiring compliance with specific UN regulations on technical specifications and cybersecurity (*UN Regulation No 155 – Uniform provisions concerning the approval of vehicles with regards to cybersecurity and cybersecurity management system [2021/387].),* and providing for specific conformity assessment procedures.

Option 4: A horizontal regulatory intervention introducing cybersecurity requirements for a broad scope of tangible and non-tangible products with digital elements, including non-embedded software.

This option differs from option 3 only as regards the scope, as it **would include non-embedded software** (critical or all) in the scope of a potential regulation. Some particular elements of the regulatory intervention may however be impacted differently as compared to option 3 as a result of the differences in scope, as highlighted below.

a) Scope:

All products with digital elements, including non-embedded (standalone) software would be covered.

Alternative **sub-options** could be considered regarding the categories of software to be covered:

> **Sub-option 4 a)** would cover only critical software: critical software, such as operating systems or web browsers, would be defined as the software which has security-critical functions or which poses similar significant potential for harm if compromised. In particular, any software that has direct software dependencies[142] upon one or more components with at least one of these attributes: (i) is designed to run with elevated privilege or manage privileges; (ii) has direct or privileged access to networking or computing resources; (iii) is designed to control access to data or operational technologies; (iv) performs a function critical to trust;[143] (v) operates outside of normal trust boundaries with privileged access. Critical software as defined above is estimated at approximately 10% out of total software market. Furthermore, cybersecurity measures for critical software were also implemented in the Unites States of America, where the mandatory cybersecurity measures imposed concerned only critical software subject to public procurement, all other measures remaining voluntary (see *Annex 6*).
>
> **Sub-option 4 b)** all software: This would reflect the fact that all types of software products contain vulnerabilities and that even software considered as low risk can serve as a stepping stone to breach a network with a view to penetrating more critical systems at a later stage of an attack chain. In addition, it is often difficult to assess the risk associated with a product before its placing on the market, as the risk to society often increased with a growing market share.

b) Requirements and obligations:

Horizontal essential cybersecurity **requirements** and corresponding obligations for operators as described above in option 3, including reporting of exploited vulnerabilities and cybersecurity incidents to ENISA, would be set out for all products with digital elements, including non-embedded software. For user-installed software [operating systems – except when the operator system is developed by the device manufacturer – and applications] and in general for non-embedded software, the responsibility for the compliance with the essential requirements would pertain to the software manufacturer.

c) Whole life cycle:

As regards market placement coverage, as in option 3, duty of care for **whole life cycle** would be provided for. This option would be even more fine-tuned than option 3 with the upcoming new EU framework for liability for defective products, considering that the latter also aims to extend liability explicitly for software.

[142] For a given component or product, other software components (e.g., libraries, packages, modules) that are directly integrated into, and necessary for operation of, the software instance in question.

[143] Categories of software used for security functions such as network control, endpoint security, and network protection.

d) Conformity assessment:

The same two **sub-options** as in option 3 would be considered with regard to the **conformity assessment procedures,**[144] corresponding respectively to **sub-options 4 a) i)** no risk categorisation, **4 a) ii)** with risk categorisation, **4 b) i**) no risk categorisation, and **4 b) ii)** with risk categorisation.

e) Interplay with other product-related legislation (notably NLF):

The interplay would be the same as set out in option 3 above *(see also for more details Annex 8).* On the specific interplay with the RED Delegated Regulation, *Annex 7* illustrates the particular differences between the two acts. In this option, the horizontal cybersecurity requirements would address even more than in option 3 the existing gaps in what the RED delegated act covers, since they would also address standalone software.

In this option, the planning of future European cybersecurity certification schemes would be more impacted than in option 3, considering that, due to the comprehensive scope, there would be much less regulatory gaps to fill in with certification in addition to what the horizontal requirements would require. However, new European cybersecurity certification schemes could emerge for products with digital elements requiring additional assurance.

How would the horizontal cybersecurity requirements set for the broadest scope in option 4 work in practice? The example of smart phones.

Smart phones would be included in the scope of the horizontal regulation (policy options 3 and 4), as they are connected hardware devices with a built-in computational logic. Under policy option 4, manufacturers of such devices would be required to implement security requirements, undergo a conformity assessment and affix the CE marking.

A smart phone consists of a large number of hardware components, such as CPUs, wireless modems, Wi-Fi chipsets or Bluetooth interfaces, which the manufacturer must acquire from other semiconductor manufacturers. Furthermore, these hardware components function thanks to firmware (i.e. embedded software that provides low-level control of the components). Therefore, in addition to the manufacturer of the smart phone, the manufacturers of these hardware components and the software manufacturers of the firmware would also be covered under the scope of a horizontal regulatory intervention (both under policy option 3 and 4).

Smart phones are also usually shipped with an operating system (non-embedded software). The smartphone manufacturer would also need to ensure the security of the operating system. In cases where the manufacturer is also the manufacturer of the operating system, the security requirements that the manufacturer is required to implement would not only cover the hardware device, but would also extend to the software.

In cases where the operating system is provided by a third party, the manufacturer would need to check the CE marking affixed to the operating system to make sure that it has been developed in line with the requirements. The manufacturer of the operating system would equally be subject to such an obligation in relation to the various software components integrated during development.

Consumers and business users, and in particular companies that are subject to supply chain security obligations could rely on the CE marking as an indicator that not only the manufacturer of the final product has taken cybersecurity seriously during the development process, but also that all hardware and software components inside the product have been developed factoring-in security.

5.3. Options discarded at an early stage

In addition to the four options presented in *section 5.2,* in the analysis of potential policy options that could address the problems described in *section 2* and reach the general and specific objectives set out in *section 4*, a number of options or sub-options, notably in relation to alternatives entailing regulatory interventions, were discarded at an early stage and therefore not assessed in further detail, as follows:

[144] Even in the case of sub-option 1.i. as regards the scope (i.e. only critical software), both sub-options could be considered, with the specification that in the sub-option entailing two levels of risks the critical software would be by default required to be subjected to third party conformity assessment, with potentially a sub-category thereof subjected to certification by national authorities.

(a). As regards the **choice of legal instrument**, the options consisting of a regulatory intervention (notably options 3 and 4) would entail the adoption of **a regulation and not a directive**. This is because, for this particular type of product legislation, a regulation would more effectively address the problems identified in *section 2* and meet the objectives formulated in *section 4*, since it is an intervention that is conditioning the placing on the internal market of a very wide category of products. The transposition process in the case of a directive for such intervention could leave too much room for discretion at national level, potentially leading to lack of uniformity of certain cybersecurity requirements, legal uncertainty, further fragmentation or even discriminatory situations cross-border, even more taking account of the fact that the products covered could be of multiple purpose or use and that manufacturers can produce multiple categories of such products.

(b). As regards the **scope of potential regulatory interventions in options 3 and 4**: Excluding the wireless products covered by the RED delegated act from the scope of the regulatory interventions envisaged in options 3 and 4 was not considered a valid sub-option. This is because the essential requirements set out in the RED delegated act are of generic nature, while covering a wide category of products (inter-connected radio equipment) that represent an important part of the overall scope considered for the horizontal cybersecurity regulatory intervention in options 3 and 4. The essential requirements in the RED delegated act alone would not sufficiently address the problems identified, as described in *section 2*, nor would they be sufficient to effectively meet the objectives set out in *section 4.* Furthermore, aspects such as duty of care or whole life cycle are not covered by the RED delegated act. Before new horizontal cybersecurity rules would start applying, important progress would have been achieved with the implementation of the RED delegated act, including preparation of standards, which would also take account of the proposal for a horizontal regulation. A smooth sequencing between the two acts would then be ensured, without generating overlapping or unnecessary burden on the relevant economic operators concerned by such obligations.

(c). In relation to the horizontal cybersecurity requirements envisaged in options 3 and 4, the sub-option of **differentiating such requirements per category of risks** was discarded at an early stage. This is because such sub-option would have been unrealistic, given that the requirements would in any case be objective-oriented and aim at setting basic requirements for introducing security by design and by default, ensuring transparency, duty of care throughout whole life cycle. These would be baseline requirements that all products with digital elements should have in place irrespective of their functionalities or intended use. The differentiation per categories of risk would rather have relevance for informing the strictness with which compliance with the requirements is assessed. It can only be reflected in more sector- or product-specific standards.

(d). As regards still the horizontal cybersecurity requirements envisaged in options 3 and 4, the sub-option of **differentiating such requirements between Business to Client (B2C) and Business to Business (B2B)** was discarded at an early stage. This is because essential cybersecurity requirements as those that would be set out through a horizontal regulatory intervention would be objective-oriented, hence the same irrespective of the use case, with the aim to ensure that security is factored in since the design and the development of the respective products. These would therefore not differ depending on the user. Furthermore, many products with digital elements are used in both settings.

(e). As regards the **duty of care throughout the life cycle** of products with digital elements, the potential legislative interventions analysed did not consider the alternative of not covering whole life cycle at all as a valid option. This type of coverage is coherent with other current legislative reviews considered, such as the EU product liability framework, and is also determined by the very nature of the requirements considered, i.e. in cybersecurity the updates are a necessity, therefore any alternative where no obligation concerning the life cycle would have been considered would not have been realistic. Furthermore, the coverage of whole life cycle is one of the aspects regarding a horizontal cybersecurity intervention for products with digital elements where the vast majority of stakeholders concur.[145]

(f). As regards market surveillance, policy options 2, 3 and 4 would plug into the New Legislative Framework. Market surveillance would therefore be based on an existing and well-established concept. As a result, governance rules for market surveillance authorities going beyond the standard NLF provisions leaving discretion to Member States on how they organise themselves was not considered as a realistic option for a first-time market intervention of this breadth.

6. What are the impacts of the policy options?

6.1. Overview of impacts on businesses, public authorities and consumers

To the extent possible, specific and aggregated quantitative estimates have been elaborated for the different sources of costs and benefits. However, the ability to develop such quantitative estimates was limited by different factors, such as the multitude of specific product markets covered by the initiative and the ability to define at granular level the markets in the scope of the different policy options. Where possible, estimates and assumptions were made. Different methodologies were used for the quantification of costs and benefits that will be indicated in the relevant sections. Furthermore, the quantitative analysis of costs and benefits uses in a consistent way for the aggregation several key assumptions that are further explained in *Annex 4*:

- **Estimation of number of products**: To estimate the number of products with digital elements on the market, the assumption of one product per manufacturer was used. The indicator extended classification (ICT-EXT-ADJ, see *section 5.1.* and *Annex 3*) for hardware was used. Combined with the indicator for software (SD), **615 272 manufacturers/products** are counted on a market that is valued in total at up to EUR 1 485 billion in turnover[146]. While it is an underestimation to count one product with digital elements per manufacturer, as large companies might develop hundreds of products, it is compensated to some extent by the choice of using a broad indicator for the hardware market. Furthermore, the aggragted estimations have been made based on the assumption that all products currently on the market would be impacted, while under policy option 3 and 4, costs would actually occur for new products being placed on the market.
- **Business as usual (BaU)**: based on available data, it is estimated that 50% of manufacturers have a systematic approach to secure product development, while for the rest, it is assumed that they have no security requirements in place. For conformity assessment, the BaU costs are estimated at 40% for hardware manufacturers, and at 25% for software manufacturers. For further background, see *Annex 4.*
- **Average product development costs**: it is estimated that on average development costs by product are of 140 000 EUR. For further background, see *Annex 4*.

For the qualitative assessments of impacts, in order to compare the policy options (and sub-options), a scale from *Neutral* to +++ has been used (with "+++" indicating the highest impact).

The table below presents an overview of the main (direct and indirect) economic, internal market, security, competitiveness, social, environmental and fundamental rights impacts and stakeholders affected that will be analysed more in detail in the following sections for each policy option.

	Affected stakeholder	**Main impacts**	
		Costs	**Benefits** (Direct and indirect)

[145] 90 % of the participants to the public consultation believe that hardware and software manufacturers should be responsible for the full life cycle of a product with digital elements (such as by providing updates), including 79 % of SME manufacturers.

[146] The methodology for the market indicators is further explained in Annex 3.

Businesses	Software & hardware manufactures	— Direct compliance costs (e.g. security requirements; information obligations; documentation; testing; reporting obligations)	— Streamlined requirements for products with digital elements — Reduced cyber incidents (costs of reputation) — Higher uptake of products with digital elements in and outside the EU (turnover)
	Importers of products with digital elements	— Direct compliance costs (familiarisation; verification)	— Higher uptake of products with digital elements in and outside the EU (turnover) — Reduced cyber incidents (costs of reputation)
	Distributers of products with digital elements	— Direct compliance costs (familiarisation; verification)	— Higher uptake of products with digital elements in and outside the EU (turnover) — Reduced cyber incidents (costs of reputation)
	Businesses as end-users	— Higher prices of products with digital elements	— Higher transparency on security properties and on secure use of products with digital elements — Reduced cyber incidents (costs of handling & reputation) — Reduced cyber mitigation costs — Reduced compliance costs to meet other EU and national cyber legislation (e.g. NIS)
	Notified bodies	— Direct compliance costs (e.g. training and new staff; accreditation framework)	— Increased turnover — Streamlined requirements for accreditation related to security of products with digital elements
Public authorities	Market surveillance authorities (MSAs)	— Direct compliance costs (e.g. training and new staff) — Enforcement costs (e.g. monitoring and inspection)	— Overall benefit of public interest of ensuring that products with digital elements accessing the internal market are secure — Cost savings due to streamlined requirements for market surveillance of products with digital elements
	Accreditation and notifying authorities	— Direct compliance costs (e.g. training and new staff) — Enforcement costs (monitoring)	— Streamlined accreditation and notification requirements — Fees from notified bodies
	Public authorities as end-users	— Direct compliance costs (e.g. familiarization for public procurement) — Higher prices of products with digital elements	— Transparency on security properties and on secure use of products with digital elements — Reduced cyber incidents (costs of handling & reputation) — Reduced cyber mitigation costs — Reduced compliance costs to meet other EU and national cyber relevant legislation (e.g. NIS)
	ENISA	— Direct compliance costs (collect and disseminate information on exploited vulnerabilities)	— Enhanced transparency on the security of products with digital elements
Consumers and citizens	Consumers and citizens	— Higher prices	— Transparency on security properties and secure use of products with digital elements — Enhanced protection of fundamental rights, especially privacy and data protection (reduced data breaches)

Table 2: Main impacts and stakeholders affected

6.2. Economic impacts

This section analyses economic impacts on businesses, SMEs, public authorities and users.

6.3.1. Impacts on manufacturers of products with digital elements and other economic operators

The impacts in terms of costs and benefits on businesses, including manufacturers, distributors and importers, will stem from, on the one side, compliance costs, and on the other side, increased reduced cyber incidents, reputation, competitiveness and increased uptake of products with digital elements. The impact on SMEs, including as economic operators, is detailed in section *6.3.2*.

Analysis of compliance costs

Direct compliance costs will impact most significantly software and hardware manufacturers. The overview of the main cost sources is summarised below:

a) **Familiarisation** with the new obligations (one-off): manufacturers, distributors and importers covered by the initiative will have to bear adjustment costs to familiarise with the obligations under the new legislation and develop compliance strategies (implementation costs).

b) **Secure product development throughout the life cycle** (one-off and recurrent), including requirements related to vulnerability handling as well as support and security updates: Adjustment costs would stem from the implementation of security controls and features into the product design and development (one-off and recurrent for checking regularly compliance and implementing updates), hiring skilled human resources, and from potential equipment and material costs (e.g. new security software). Security controls and features would also include obligations to communicate and inform end users on the lifespan of the product and provide security support.

c) **Information and transparency requirements** to end-users on secure product properties and instructions for use (one-off and recurrent): Adjustment costs would stem from information obligations on the security properties and use of the digital product.

d) **Conformity assessment:** internal product testing/self-assessment, one-off costs, e.g. for the purchase of laboratory and testing equipment for internal testing, and recurrent costs, e.g. for the recalibration of testing equipment and reporting, as well as third-party product testing and certification (one-off for the certification fees and recurrent for maintenance of the certification, e.g. regular audits). For more background on testing costs, see *Box 2*.

e) **Other conformity costs and reporting obligations:** companies will need to develop a technical documentation and a declaration of conformity, affixing marking on products and report on the conformity of products at the request of authorities as well as reporting of exploited vulnerabilities and incidents to ENISA. Internal systems and procedures need to be put in place to ensure that the technical documents and declaration of conformity are updated regularly. Furthermore, vulnerability and incident reporting requirements will represent both one-off and recurrent costs for businesses (e.g. to set up the reporting systems and to report regularly on events).

Quantitative estimates are provided to the extent possible, and mostly available for policy options 3 and 4. Due to the limited data available, the provided estimates only represent average and abstract figures. It could not be distinguished between one-off and recurrent costs. In general, as highlighted by stakeholders,[147] the **compliance costs for a company will greatly vary depending on: (i) the complexity and size of the product; (ii) the existing security practices of a given company; (iii) the environment (B2C vs. B2B), and (iv) the size of the company.**

Unless specified, the quantitative estimates express additional compliance costs, taking into account the Business as Usual (BaU) costs. BaU costs capture existing costs in the absence of any policy measure. *Box 1* summarizes the methodological steps, assumptions and limitations.

[147] Stakeholder workshop of 10 May 2022 organised by the study supporting this impact assessment, see *Annex 2*.

Summary and limitations of methodological approach on quantification of compliance costs

In order to estimate the direct compliance costs for businesses, the following steps have been taken:

1. *First, the relevant stakeholders that would be impacted by direct compliance costs have been identified. This includes economic operators subject to direct obligations, i.e. manufacturers (of software and hardware), distributors and importers.*
2. *The different cost sources that would affect the economic operators were identified and verified through stakeholder consultations, including the public consultation and targeted workshops and surveys (see Annex 2).*
3. *For each cost source, estimates on the product development costs were gathered from **primary and secondary sources**. The data that could be gathered is limited. Only one primary source estimation was used for the cost source related to documentation and reporting under policy option 3 and 4, however this cost estimation could not be verified. Secondary data was used for major cost estimates, such as conformity assessment and secure product development. No cost estimates could be made for a number of costs sources, such as familiarisation with the requirement of the initiative and providing information to users.*
4. *Where data could be found, **average cost estimates for an abstract product unit** were made. On this basis, the costs were aggregated for the market in the scope of the relevant policy option. The Standard Cost Model could not be applied due to limited data available.*
5. *In order to **aggregate the costs**, the **number of products with digital elements** that would be impacted was estimated, taking into account a general assumption of BaU costs, and multiplying by the average product unit costs. The main product markets were identified, respectively the software and hardware market, based on the ICT-EXT-ADJ and SD market indicators (see Section 5.1. and Annex 3), and the scope of the relevant policy options were delineated to the extent possible. In some cases (e.g. for critical software), assumptions for the market share had to be done due to a lack of granularity of market data. In order to apply the BaU costs, assumptions have been made on the percentage of businesses already implementing the relevant measures, as detailed in Annex 4.*

Box 1: Overview of methodological steps for the quantitative analysis of compliance costs

Policy option 1

Given that the measures will be voluntary, under this option only the participating **manufacturers** would bear possible additional adjustment and administrative costs. As these costs would depend on the engagement of the manufacturers into voluntary initiatives, it is not possible to give aggregated cost estimates. Under policy option 1, there would be no direct compliance costs on **importers** and **distributors.**

Adjustment costs for manufacturers would stem from implementing security requirements as foreseen in relevant guidelines or recommendations. To estimate the costs of secure product development, secondary data was used, which is the Venson calibration model (further developed in *Annex 4*). According to this academic research, implementing a secure product development life cycle approach, without any requirements in place, would on average add 30.5% of product development costs (if no comprehensive security measures are in place). **Administrative costs** would be linked to third-party conformity assessment procedures to be carried out under voluntary EU certification schemes, and could range between EUR 25 000 to 40 000 per product, according to secondary data[148].

The economic cost impact of option 1 is likely to be low on manufacturers, and neutral on distributors and importers. The BaU costs are expected to be high as the manufacturers participating to voluntary initiatives are likely to be the more security-minded. Furthermore, it can be assumed that those manufacturers participating in such voluntary measures would expect any additional costs to be offset by direct or indirect benefits (e.g. increase their reputation and market share).

[148] SWD(2017) 500 final, IA accompanying the Cybersecurity Act, based the costs of national cybersecurity certifications

For this policy option, stakeholders indicated in the public consultation **low to medium costs** (on average 2.5, with 5 being the highest) with the highest average costs for the compliance with guidelines on public procurement.[149] For communications, guidance and recommendations, stakeholders indicated on average the cost would be medium[150]. The use of voluntary European cybersecurity certification, on the basis of the Cybersecurity Act, was rated as **high** by software and hardware manufacturers.[151] Despite being voluntary, business representatives stressed that certification involves costs when it is required by customers. At the same time, the possibility to obtain an EU wide certificate would reduce costs for those manufacturers that already certify their products or would act as an incentive for those willing to do so.[152] Such certification costs would in any case occur in the status quo as well, therefore the BaU costs would be high.

	Costs (administrative and adjustment costs)
Commission (voluntary) recommendations and guidance	• Secure product development costs for those manufacturers that decide to apply the measures = +30.5% of product development costs if no BaU costs, on average EUR 42 700 for a product unit cost of EUR 140 000. • No costs for importers and distributors
Additional (voluntary) EU certification schemes	• Compliance costs for manufacturers that engage in EU certification (ca. EUR 25 000 to 40 000 for certifying a product[153]) • No costs for distributors and importers
Total	*Neutral/+*

Table 3: Overview of compliance costs on businesses under policy option 1

Policy option 2

Under this policy option, direct compliance costs for hardware and software manufacturers (for embedded and possibly non-embedded software), as well as distributors and importers would stem mainly from the amendment and addition of cybersecurity requirements in already existing and future NLF legislation. Such amendments would address new risks as they emerge, including potentially for non-embedded software.

When asked in the public consultation, stakeholders rated on average the costs of this option as **medium to high** with 3.36 out of 5 (with 5 indicating very high costs). Hardware manufacturers rated the costs related to this option higher than software manufacturers (4.06 vs. 3.73 out of 5).

In relation to compliance costs, two main situations can be distinguished, depending on whether non-embedded software is brought into the scope through amending an NLF legislation or not.

- If only hardware manufacturers and manufacturers of embedded software would be concerned, the BaU costs for hardware manufacturers are expected to be high. The amendment of existing NLF legislation would imply, for a given product, adjustment costs related to the familiarisation and additional security and information requirements linked to the lifecycle approach and increased transparency. Option 2 foresees no specific conformity rules for cybersecurity requirements only. Therefore, minimal extra administrative costs would be foreseen (e.g. mainly updating technical documentation and the declaration of conformity). Since it would be determined on a case-by-case basis whether amendments are necessary, it was not possible to make general quantitative cost estimations.
- If non-embedded software manufacturers are to be covered by any amendment of existing or future NLF legislation, those manufacturers would bear high compliance costs. The

[149] The costs were estimated to 2.97 in average, with hardware manufacturers rating it 2.9 and software manufacturers 2.83.
[150] rated the costs at 2.54 out of 5 (with 5=very costly). Software manufacturers indicated a slightly higher cost (2.69) compared to hardware manufacturers (2.2).
[151] 3.05 and 3.31 out of 5 respectively for hardware and software manufacturers.
[152] See also SWD(2017) 500 final, IA accompanying the Cybersecurity Act.
[153] SWD(2017) 500 final, IA accompanying the Cybersecurity Act, based the costs of national certifications

aggregated costs would depend on the specific sector and the market share of such software.

- **Possible amendment of RED delegated act/Directive to include non-embedded software:**

As outlined in the baseline scenario in *Section 5*, if the RED delegated act would be amended to cover non-embedded software, additional adjustment and administrative costs would occur only to a limited extent for hardware manufacturers already subject to the RED delegated act (i.e. mainly related to lifecycle approach) and would mostly occur for non-embedded software manufacturers. Furthermore, distributors and importers would bear additional familiarisation costs. The cost estimation will focus on the costs on manufacturers of non-embedded software into the scope of the RED delegated act.

Based on the market analysis data available (see *Annex* 3), the assumption was made that all non-embedded software would be covered by this measure. To estimate the **adjustment costs** of secure product development, secondary data was used, which is the Venson calibration model that foresees 30.5% additional product development costs if nothing is in place (further explained in *Annex 4*). This leads to 42 700 EUR additional costs for a product unit when considering an average product development cost of EUR 140 000[154]. Furthermore, the assumption was made that 50% of software manufacturers already implement secure requirements (further explained in *Annex 4*). Taking the SD indicator (see market analysis in *Section 5* and *Annex 3*), and assuming one product per software company, the **software secure development costs** would amount to **EUR 7.8 billion**[155]. While this figure is likely an underestimation for the whole software market (as there are likely more software products), it goes beyond the scope of the measure (which would cover only wireless products).

Software manufacturers would also bear new adjustment and administrative costs related to conformity assessment (self-assessment) and other obligations linked to conformity. Secondary data was used to estimate the average costs for self-assessment, which is EUR 18 400 per self-tested product (2 staff per month)[156]. Taking the same market scope, and assuming that 25% of the software manufacturers would already apply a similar form of testing[157], additional testing costs would amount to **EUR 5.1 billion**. Other conformity obligations (technical documentation, CE marking, declaration of conformity and reporting of exploited vulnerabilities and cyber incidents) would amount to **EUR 4.6 billion**, using a primary estimate of 9% average additional product development costs that could however not be verified[158]. Hence, the total aggregated compliance costs for software manufacturers would amount to **EUR 17.5 billion.**

	Costs (administrative and adjustment costs)
Amending security requirements in sectoral NLF legislation	*Depending on the sector where the legislation is amended* • For manufacturers: - Adjustments costs for secure product development (on average 30.5% if no BaU) - Familiarisation costs and updating technical documentation and conformity documentation • For importers and distributors: familiarisation costs
Bringing non-embedded SW into the scope of some NLF legislation and	• For manufacturers: - For software: **total compliance costs of EUR 17.5 billion** (not including familiarisation and information obligations)

[154] This assumption is further explained in Annex 4.

[155] 50% of 365 759 products, multiplied by 42 700

[156]Study on the need of Cybersecurity requirements for ICT products – No. 2020-0715 Final Study Report

[157] The assumption of 25% is further explained in *Annex 4*.

[158] Targeted survey on impacts launched on 16 May 2022 organised by the study supporting this impact assessment. This estimate is likely leading to an overestimation as it brings the conformity costs close to the costs of testing. However, no other estimate could be found in primary and secondary data, and it was suitable to take into account these costs to estimate the administrative costs.

potentially duty of care for whole life cycle (e.g. RED DA)	- Limited adjustment and familiarisation costs for hardware manufacturers • For importers and distributors: familiarisation costs
Total	+/++

Table 4: Overview of compliance costs on businesses under policy option 2

Policy option 3

Under policy option 3, compliance costs, both adjustment and administrative costs, would occur for all hardware manufacturers and embedded software manufacturers, as well as importers and distributors, due to the horizontal security requirements, associated conformity assessment and documentation and reporting requirements. The main costs for importers and distributors would be adjustment costs related to familiarisation related to the new requirements.

The impacts of policy option 3 will depend on the sub-options related to conformity assessment, respectively in sub-option 3 i) and 3 ii). In a first stage, only voluntary measures would apply to non-embedded software ("staggered approach). These cost impacts are described under option 1, and are not possible to be quantified. Furthermore, due to the lack of granularity of the market analysis, the aggregated impact on embedded software could not be estimated precisely.

In the public consultation, stakeholders rated the costs of "*Introducing mandatory horizontal cybersecurity requirements for hardware products*" on average at **medium to high**, with 3.55 out of 5 (with 5 indicating very costly).

Regarding **adjustment costs**, the main cost source will be related to secure product development. To estimate these adjustment costs, secondary data was used, which is the Venson calibration model that estimates an average of 30.5% additional product development costs if no security is in place (further explained in *Annex 4*). This leads to 42 700 EUR of additional product development costs for an average product with digital elements unit (EUR 140 000). Taking the assumption that 50% of hardware manufacturers are already implementing adequate security requirements (further explained in *Annex 4*), and estimating the number of hardware products impacted by using the ICT-EXT-ADJ indicator, the **aggregated additional costs** related to secure product development would be of EUR **5.33 billion**[159].

Adjustment costs related to **familiarisation costs** and costs related to **transparency and information** could not be estimated due to a lack of available primary and secondary data. For instance, in the case of the Toy Safety Directive, for importers, the time spent to comply with the Directive's requirements equalled to 110 man-hours per toy type (EUR 2 500). For distributors, time spent to comply with the Directive's requirements: 86 man-hours per toy type (EUR 1 953).[160] According to the targeted survey[161], the costs related to information and transparency would not be significant if provided in digital format.

Regarding **conformity assessment costs**, they are expected to vary depending on the sub-options related to conformity assessment. The average costs of conformity assessment per product with digital elements was drawn from secondary data. For self-assessment, the average cost was estimated at EUR 18 400 including one-off and recurrent costs (see *Box 2*). For third-party assessment, costs were estimated at EUR 25 000, which represents an average of possible costs for different types of products based on secondary data. *Box 2* further discusses the costs of self-assessment and third-party assessment. Costs related to conformity assessment would be both adjustment costs in the case of self-assessment (e.g. setting up and maintaining testing facilities)

[159] 50% of 249 513 hardware products (based on ICT-EXT-ADJ), multiplied by 42 700 EUR

[160] Evaluation of NLF Regulation (2021)

[161] Targeted survey on impacts launched on 16 May 2022 organised by the study supporting this impact assessment

as well as administrative costs linked to certification fees paid to notified bodies to carry out audits and review documentation.

Under both sub-options **3i)** and **3ii)**, the **BaU costs** for conformity assessment for hardware manufacturers have been assumed to be on average at 40% both for self-testing and third-party assessment. This figure represents a low average of BaU cost evidenced. In the context of the Impact Assessment of the RED delegated act[162], the BaU for hardware products varied between 30 % for more simple products to 90 % for complex products such as routers. No data could be found on BaU costs for internal testing. These assumptions and estimates have **several limitations**:

- In the case of self-assessment (policy option 3i)), for hardware manufacturers already covered by NLF legislation (in particular RED), the BaU would likely be higher, as they could either follow the existing approaches on conformity assessment. The additional costs would mainly apply to non-wired hardware products on the market, of which the precise share could not be estimated[163]. Some of these manufacturers of non-wired hardware would likely also have internal testing practices in place.
- The BaU costs and additional testing costs would in practice greatly vary depending on the complexity of the product, as evidenced by the Impact assessment of the RED delegated act[164]. The costs increase with the complexity of the product, therefore it can be assumed that consumer products would generally bear lower costs for testing compared to industrial products. The BaU costs might be equally lower in the B2C compared to B2B sector, the latter being typically bound by more detailed contractual responsibilities. Therefore, the additional costs related to conformity assessment are expected to be higher on consumer products higher than for business products (for examples, see *Box 2*)**.**

Under **sub-option 3i)**, taking into account the BaU factor of 40% and the number of products based on the ICT-ADJ-EXT market indicator, and counting on average EUR 18 400 of internal testing by product, the aggregated additional costs related to the conformity assessment for the hardware market are estimated at **EUR 2.8 billion**[165]. Under **sub-option 3ii)**, taking into account the same BaU factor and market indicator, and the average costs of EUR 25 000 for third party assessment and assumig that the share of critical products should be narrow (ca. 10% of the market), the aggregated additional costs related to the conformity assessment for the hardware market are estimated at **EUR 2.9 billion**[166].

Other costs related to conformity, such as the technical documentation, the declaration of conformity, affixing of the CE market and reporting of exploited vulnerabilities and cybersecurity incidents to ENISA, have been estimated (using the estimate of additional 9% of product development costs based on primary data[167]) at **EUR 3.1 billion** for the hardware market.

As a result, in total, under policy **option 3 sub-option i)**, the total additional aggregated compliance costs (adjustment and administrative) would be of **EUR 11.2 billion**. Under policy **option 3 sub-option ii)**, additional aggregated compliance (adjustment and administrative) costs would be of **EUR 11.3 billion.** These figures do not include the costs for embedded software manufacturers, and therefore might be an underestimation.

	Testing costs	Other conformity costs	**Total conformity costs** (adjustment and administrative costs)	**Adjustment costs for secure product development**	**Total compliance costs**

[162] See *Annex 4*, and SWD(2021) 302 final, IA supporting the RED delegated act
[163] This could include for instance wired IoT devices or computer components, including chipsets, memory chips or processors.
[164] SWD(2021) 302 final, IA supporting the RED delegated act
[165] 60% of 249 513 products, multiplied by EUR 18 400
[166] 60% of 249 513 products, with 10% doing third-party assessment (average costs of EUR 25 000)
[167] Targeted survey on impacts launched on 16 May 2022 organised by the study supporting this impact assessment

3(i) self-assessment	EUR 2.8 bn	EUR 3.1 bn	EUR 5.9 bn	EUR 5.3 bn	EUR 11.2 bn
3ii) third-party assessment	EUR 2.9 bn - EUR 2.5. bn (self-assessment) - EUR 0.4 bn EUR (third-party assessment)	EUR 3.1 bn	EUR 6 bn	EUR 5.3 bn	EUR 11.3 bn
Voluntary approach on SW	See PO1				

Table 5: Overview of aggregated compliance costs on businesses under policy option 3.

Both under policy option 3 and 4, an important source of compliance costs would stem from the conformity assessment. Depending on the sub-options, third-party assessment would be foreseen for a narrow share of the market. Self-assessment (or internal testing) is generally seen as less costly than third-party assessment as it does not involve any notified body. However, the stakeholder consultations did not enable to make precise cost estimates to reflect the difference between the two assessment procedures. Business stakeholders generally stressed the importance for the manufacturer to have **flexibility** regarding the procedure.

Self-assessment of a product with digital elements typically includes (i) setting up an internal testing laboratory (one-off adjustment cost, e.g. train and hire staff); (ii) internal testing of a product with digital elements (recurrent). **Third party assessment** of a product with digital elements includes: i) the review of the technical documentation by a notified body; and ii) the testing and audit of the technical characteristics of the product with digital elements itself.

Throughout the consultations, stakeholders expressed different opinions as to whether self-assessment would be more or less costly compared to third-party assessment. During a consultation workshop,[168] most respondents said that the impact on costs of internal product testing/self-assessment would be "Low", followed by "Medium". Some stakeholders stressed that the costs will be less than third-party conformity assessment, and could be easily integrated in the internal product development process.[169]

During the same workshop, according to stakeholders, the impact on costs of external third-party product testing (or certification) would be "High", followed by "Very high". On the contrary, during the targeted survey,[170] interviewees stressed that one-off costs for self-assessment testing are quite high as it demands building internal capabilities, which could be cumbersome for SMEs.[171] The recurrent costs of self-assessment could be lower once internal capabilities have been put in place, while there would be higher recurrent costs for third-party assessment. In the context of the targeted survey, operating expenses (OPEX) – recurrent costs were estimated between EUR 3 000 and EUR 5 000 per product. Similarly, secondary data shows that the costs for internal testing for a laptop were estimated at EUR 5 000 per unit.[172] The stakeholders' feedback and estimated costs could be summarised as follows:

	Type of cost		
Testing method	*One-off costs*	*Recurrent*	*Average (estimation)*
Self-assessment	+/++	Neutral/+ (around 30%)	EUR 18 400
Third-party assessment	Neutral/+	++	EUR 25 000

The costs related to self-assesment and third-party assessment heavily depend on the complexity of the product, in particular in terms of supply chain involving different hardware and/or software manufacturers.

[168] Stakeholder workshop of 10 May 2022 organised by the study supporting this impact assessment, see *Annex 2*.

[169] Several others stressed that such self-assessment should occur during the internal product development process, which would also allow to keep the costs low.

[170] Targeted survey launched on 16 May 2022 conducted by the study supporting this impact assessment.

[171] Idem.

[172] European Commission (2014): "Commission Staff Working Document, Part 2: Results of the case studies, A vision for the internal market for products", page 54, https://eur-lex.europa.eu/resource.html?uri=cellar:6da8f15b-8438-11e3-9b7d-01aa75ed71a1.0001.05/DOC_1&format=PDF.

In order to estimate average costs, the following cost estimates from secondary data were used:

- In the Cybersecurity Act's Impact Assessment study,[173] it was estimated that costs (average recurrent and one-off) might potentially be higher than EUR 18 400 in staff costs, which corresponds to two FTE months for an average firm with an hourly rate of ca. EUR 29. No other secondary sources could be identified.
- For the *EU Cybersecurity Act*, in France the Certification Sécuritaire de Premier Niveau (CSPN) costs were estimated between EUR 25 000 to EUR 35 000, while in the Netherlands the Baseline Security Product Assessment (BSPA) were estimated on average at EUR 40 000.[174] For the delegated act of the RED, the cost estimations ranged from EUR 5 000 to EUR 50 000 or more, depending on the product.[175] Hence, an average of EUR 25 000 was chosen to estimate the costs of third-party assessment. As a matter of comparison, the benchmark averages in the Study to support the IA of the *Artificial Intelligence Act* lie between EUR 16 800 and 23 000[176].

Examples of testing costs for products[177]

- For testing connected garden equipment (consumer product), the costs would be of 25 000 EUR, while the BaU costs would be of only 20%.
- The costs of third-party assessment will increase with the complexity of the product, while for such products, the share of BaU costs would also typically be higher (70 to 90%). For example, for a more complex product, like a router, the total costs are estimated at EUR 126 000, with a BaU costs of 90%.
- For software intended for telecom networks and complex IT-systems (in the scope of policy option 4), self-assessment would cost around 30 000-50 000 EUR, with BaU costs of 90%.

Box 2: Costs of conformity assessment for policy option 3 and 4.

Policy option 4

Under this policy option, all hardware and software manufacturers (depending on the sub-options), as well as distributors and importers, would bear additional compliance costs. As for policy option 3, the main costs for importers and distributors would be familiarisation costs. The costs of policy option 4 will depend on the sub-options related to the scope (4a) and (4b) and conformity assessment (i) an (ii). The detailed market analysis (*Annex 3*) did not enable to estimate the share of **critical non-embedded software**, therefore the assumption was made that it would represent less than 10% of the software market[178]. As in policy option 3, the market analysis did not enable to distinguish between embedded and non-embedded software, therefore the cost estimates are provided for the software market in general.

When asked in the public consultation about the costs of *introducing mandatory horizontal cybersecurity requirements for software products,* stakeholders indicated **medium to high costs** on average (3.68 out of 5). Hardware manufacturers rated the costs slightly lower (3.47) than software manufacturers (4.42 out of 5). As mentioned, for *introducing mandatory horizontal cybersecurity requirements for hardware products,* stakeholders indicated on average **medium to high costs** (3.55 out of 5). Taking the questions together, software manufacturers indicated in average "**high to very high costs"** (4.21 out of 5) compared to hardware manufacturers, who rated the costs "**medium to high"** (3.47 out of 5).

When consulting stakeholders, most respondents said that the impact of implementing security requirements relating to features of the products with digital elements and related to vulnerability management would be "**Medium**", followed by "**High**".[179] The impact on costs of implementing

[173] Study on the need of Cybersecurity requirements for ICT products – No. 2020-0715 Final Study Report
[174] SWD(2017) 500 final, IA accompanying the Cybersecurity Act.
[175] SWD(2021) 302 final, IA accompanying the RED Delegated Act..
[176] Study to Support an Impact Assessment of Regulatory Requirements for Artificial Intelligence in Europe, final report (D5).
[177] SWD(2021) 302 final, IA supporting the RED delegated act
[178] The product categories that are considered to be critical will be defined in such a way that they should not represent a significant share of the market. Taking the whole market of products with digital elements, critical products with digital elements that need to undergo third-party assessment should be limited and not represent more than 10% of the total market. In order to estimate the costs, each time 10% of the total costs for the software market were added.
[179] Stakeholder workshop of 10 May 2022 organised by the study supporting this impact assessment, see Annex II.

requirements relating to security updates, end of life and whole life cycle would be **"High"**, followed by "Medium".

Under policy option 4, based on the available quantitative cost estimates,[180] and depending on the sub-options, the following **aggregated compliance costs** could be estimated:

Regarding **adjustment costs**, the same approach is taken as in previous sections on estimating secure product development costs: secondary data was used, which is the Venson calibration model that estimates an average of 30.5% additional product development costs if no comprehensive cybersecurity measures are in place (further explained in *Annex 4*). This leads to 42 700 EUR of additional product development costs for an average product with digital elements unit (140 000 EUR). The assumption that 50% of manufacturers are already implementing adequate security requirements (further explained in *Annex 4*) is taken.

The aggregated adjustment costs vary depending on sub-options related to the scope of the initiative. Under **policy option 4 a)** only 10% of the software market (assumption for share of critical software) would be impacted and the whole hardware market. By estimating the number of products with digital elements concerned using the SD and ICT-EXT-ADJ indicators, aggregated additional costs related to secure product development are of **EUR 6.11 billion**. Under **policy option 4 b)**, the full software and hardware markets would be impacted. By estimating the number of products with digital elements concerned using the ICT-EXT-ADJ and SD indicators, it leads to aggregated additional costs of **EUR 13.13 billion**.

As for policy option 3, costs for manufacturers, distributors and importers related to **familiarisation** could not be estimated, but would occur under all sub-options. The costs related to **information and transparency** for manufacturers to the end-users could not be estimated. According to the targeted survey[181], the impact on costs of implementing requirements related to transparency, guidelines and user information would be **"medium"**, followed by **"low"**. Respondents specified that the costs related to transparency and information would not be significant if provided in digital format.

Regarding the **conformity assessment costs**, they will vary for policy option 4 a) and b) depending on the sub-options related to conformity assessment. The average costs of testing by product with digital elements was drawn from secondary data, as explained in *Box 2*. These costs would be both adjustment costs in the case of self-assessment (e.g. setting up and maintaining testing facilities) as well as administrative costs linked to certification fees paid to notified bodies. The average cost for self-assessment was estimated at EUR 18 400, and for third-party assessment at 25 000 EUR (see *Box 2* above). As explained in policy option 3, the BaU factor for hardware manufacturers was estimated at 40%. For software manufacturers, it is assumed that the BaU factor would be lower, given that less software products are today covered by NLF legislation. In the absence of any data, an average BaU of 25 % was chosen, to reflect the feedback received from stakeholders that at least for more complex software products, testing, including third-party assessment, would be in place, and that testing was to some extent alredy carried out during the product development process.

Taking into account the BaU factor of 40% and 25% respectively for hardware and software products, and estimating the number of products based on the ICT-ADJ-EXT and SD indicators, the aggregated additional costs related to conformity assessment are summarised in the table below. It was assumed that third-party assessment would apply to 10% of the concerned products considered critical under policy options 4 (a)(ii) and 4(b)(ii).

[180] Several sub-options exist depending on the conformity assessment required, and whether only critical or all software would be covered. It was not possible to estimate the share of the software market represented by critical software, due to a lack of granularity in available market statistics. No distinction was made between option 4 (i) and 4 (ii) in terms of average costs related to testing given the lack of granular data, and it was assumed that no costs wold be passed on to the end-user.

[181] Targeted survey on impacts launched on 16 May 2022 organised by the study supporting this impact assessment

In addition, the administrative costs related to documentation and reporting (e.g. technical documentation, declaration of conformity, affixing of the CE market and reporting of exploited vulnerabilites and cybersecurity incidents to ENISA), have been estimated with the followng assumptions: 9% of additional product development costs (see policy option 3); an average unit cost of EUR 140 000, and a number of products based on the ICT-ADJ-EXT and SD indicators. The results are summarised in the table below.

	Testing costs (adjustment and administrative costs)	Other conformity costs (administrative costs)	***Total conformity costs***	**Adjustment costs for secure product development**	**Total compliance costs** (adjustment and administrative costs)
4(a)(i) self-assessment	3.3 bn EUR[182]	EUR 3.6 bn	*EUR 6.9 bn*	EUR 6.1 bn	**EUR 13 bn**
4(a)(ii) third-party assessment	3.4 bn EUR - EUR 3 bn (self-assessment) - EUR 0.4 bn (third-party assessment)	EUR 3.6 bn	*EUR 7 bn*	EUR 6.1 bn	**EUR 13.1 bn**
4(b)(i) self-assessment	EUR 7.9 bn[183]	EUR 7.8 bn	*EUR 15.7 bn*	EUR 13.13 bn	**EUR 28.8 bn**
4(b)(ii) third-party assessment	EUR 8.1 bn - EUR 7 bn (self-assessment) - EUR 1.1 bn (third-party assessment)	EUR 7.8 bn	*EUR 15.9 bn*	EUR 13.13 bn	**EUR 29 bn**

Table 6: Overview of aggregated compliance costs on businesses by sub-option under policy option 4

Overview of benefits for businesses for all policy options

In policy option 1, the uptake of voluntary measures would be driven by market considerations (cost-benefit analysis) such as enhanced reputation as well as participation in public procurement procedures. It is likely that the manufacturers of the most problematic cheap equipment and software would not join a voluntary initiative as this would not be in line with their business strategy. The positive impact in terms of reduced cybersecurity incidents (*see section 6.6*), uptake of product with digital elements by EU users (*section 6.3.4*) and global competitiveness and innovation (*section 6.4*) would be limited and depend on the market uptake of voluntary initiatives. In addition, the absence of horizontal legislation would drive significant compliance costs and complexity (*see section 6.3*).

In policy option 2, similar to option 1, the positive impact in terms of cybersecurity incidents (*see section 6.6*), uptake of products with digital elements by EU users (*section 6.3.4*) and global competitiveness and innovation (*section 6.4*) would be limited to certain categories of hardware products, and if at all, to certain non-embedded software products used in a specific sector. In addition, the absence of horizontal legislation will drive significant compliance costs and complexity (*see section 6.3*).

In policy option 3, hardware manufacturers would benefit from a reduced number of cybersecurity incidents (see also *section 6.6*), although the impact would be limited by the fact that non-embedded software is not covered by a horizontal initiative in the first stage. The uptake of CE

[182] self-assessment costs for hardware and 10% of the software market taking into account BaU costs and an average cost of EUR 18 400 EUR by company

[183] Self-assessment costs for hardware and software market taking into account BaU costs and an average cost of EUR 18 400 by company.

marked tangible products by EU users and globally is expected to increase (*sections 6.3.4* and *6.4*). The initiative would have a positive impact to prevent internal market fragmentation for all tangible products (*sections 6.3*).

Under policy option 4, both software and hardware manufacturers would benefit from a reduced reputational fallout following a decrease in the number of cybersecurity incidents of ca. 33% affecting their products (see also *section 6.6*). Furthermore, businesses would also benefit from enhanced supply chain security as users of products with digital elements. The uptake of CE marked software and hardware products would likely increase in the EU and globally, strengthening the EU's technological leadership. Furthermore, both software and hardware manufacturers would benefit from the prevention of internal market fragmentation (*section 6.3*).

As stressed by stakeholders in public and targeted consultations, in **policy option 3 and 4**, compliance costs could be substantially **off-set** by **alignment** with **existing European and international standards**. These standards will be taken into account in the standardisation process for harmonised standards that would follow the adoption of the initiative under policy option 3 and 4. The work related to standardisation is further developed under *Section 6.5*. It should also be noted that the compliance costs can be off-set by **transferring costs to the end-user**, which will be further developped under section 6.3.4.

Cost savings for businesses due to reduced cyber incidents under policy options 3 and 4

As a European regulation introducing horizontal requirements would trigger more than half of manufacturers to introduce a secure development product lifecycle, it is estimated that policy option 4 and 3 could reduce the cybersecurity attack surface of products with digital elements respectively by between 20 % to 33 % for policy option 4 b) and by between 10 % and 16 % for policy option 3, and hence reduce the costs related to cybersecurity incidents for businesses.

These numbers are rough estimates of when the regulatory intervention would be fully applicable and the standardisation process has concluded. Assumptions include that currently less than 50% of manufacturers[184] (see also *Section 2.2*) follow a systematic approach to security and that a secure SDLC can reduce the number of critical vulnerabilities by 66 %. The latter number draws on a study showing that, after introducing its SDLC in 2004, Microsoft was able to reduce the number of critical vulnerabilities in its product by a range of 66 %[185] (see also *Section 6.5*). Furthermore, estimates of the share of incidents resulting from exploits against weaknesses in the computational logic and design of software range from 62 % to 90 % for operators of essential services identified under the NIS Directive[186]. It is assumed that this share is valid for the whole economy. Based on the market analysis presented in *Section 5.1.*, the hardware market, to which option 3 would apply at first, is estimated to make up 48 % of all products with digital elements, while the software market is estimated to make up 52 %. Under option 4 a), the market share of critical software is estimated to represent 10% of the software market[187]. Both under policy option 3 ii) and 4a)ii) or 4b)ii), it is not possible to make any assumption related to the impact of third-party assessement on vulnerability reduction and cost savings related to cybersecurity incidents.

Taking into account all the above-mentioned assumptions:

Under policy option 3, it can be estimated that the cybersecurity attack surface would be approximately decreased by 16%, if we assume that broadly all incidents are the results of vulnerabilities. This number takes into account that 50% of the hardware manufacturers

[184] Security (2020): "Survey reveals nearly 50% of organizations knowingly push vulnerable software".

[185] Fonseca and Vieira (2013): "A Survey on Secure Software Development Lifecycles", *Software Development Techniques for Constructive Information Systems Design*, p. 12.

[186] Calculation based on the preliminary results of a still ongoing survey commissioned by ENISA and executed by Gartner (2022): NIS Investments Study 2022.

[187] which represents 38.853 companies ; the assumption is also used for the *compliance costs under Policy option 4* in the same section

(representing 48% of the concerned market) will implement a secure product development cycle. On the contrary, if considering that only 62% of the incidents are due to vulnerability exploitation, according to the lower estimate of the ENISA study mentioned above[188], this would lead to a reduction of the cybersecurity attack surface by 10%.

Under policy option 4 a), in addition to hardware manufacturers, 50% of the manufacturers of critical software would implement a secure product development cycle (taking into account the BaU). Critical software is estimated to represent 10% of the software market. Hence compared to policy option 3, it is estimated that the cybersecurity attack surface would be reduced by **11% to 18 %**, respectively reflecting scenarios where only 62% of the incidents are due to vulnerabilities or all incidents. This estimation leads most likely to an underestimation as critical software plays a specific role in the cybersecurity of products.

Under policy option 4 b), in addition to hardware manufacturers, 50% of the manufacturers of all software manufacturers would would implement a secure product development cycle. Hence, it is estimated that the cybersecurity attack surface would be reduced by **20 to 33%**, respectively reflecting scenarios where only 62% of the incidents are due to vulnerabilities or all incidents. This is a reasonable expectation, considering that building in security in the build-up of the product and ensuring effective vulnerability handling are the most effective means of addressing cybersecurity threats and incidents in products. As attackers usually need to chain multiple vulnerability exploits together to achieve their final objective, a reduction of vulnerabilities by 33 % could potentially thwart an even larger number of attacks.[189]

The initiative is designed to work in concert with the NIS2 Directive, which will require around 110 000 medium-sized and large firms to take appropriate security measures, including measures to prevent incidents. As a result, both the horizontal requirements for products with digital elements and NIS2 combined will lead to fewer vulnerabilities in products with digital elements, more security patches provided by manufacturers and faster patching of security holes by critical infrastructures and other essential entities.

In light of the above, option 3 could lead to a reduction of cybersecurity incidents by between 10 % and 16 % and as a result reduce the costs associated with cybersecurity incidents by a similar percentage. While estimates regarding the costs associated with cybersecurity incidents are not available at European level, data for certain Member States exists. Based on an extrapolation of incident-related data available for Germany (see *Box 3*), it is estimated that under this option the initiative could lead to a reduction in costs stemming from security incidents affecting companies by between **EUR 90 billion to EUR 140 billion annually**.

Option 4a), which would cover hardware and critical software, could lead to a reduction of cybersecurity incidents by **11% to 18%** and and reduced incident-related costs by a similar percentage. Using the data available for Germany (see *Box 3*), it is estimated that option 4 b) could lead to an EU-wide reduction in costs stemming from incidents affecting companies by between **EUR 97 billion to EUR 158 billion annually.**[190]

Option 4b), which would not only cover hardware but also software, could lead to a reduction of cybersecurity incidents by between 20 % and 33 % and reduce incident-related costs by a similar percentage. For instance, the annual costs associated with data breaches and DDoS attacks, which represent only a small subset of all types of security incidents, could be reduced by EUR 2.0 billion

[188] Calculation based on the preliminary results of a still ongoing survey commissioned by ENISA and executed by Gartner (2022): NIS Investments Study 2022

[189] For example, if a specific privilege escalation vulnerability becomes unavailable, other stages of an attack, such as lateral movement and or data theft may no longer be possible.

[190] There are no aggregate estimates of the cost of security incidents in Europe. The figure was calculated using the cost of cybersecurity incidents in Germany and by extrapolation using the share of German GDP in European Union GDP. The aggregate cost of security incidents in Germany amounted to EUR 220 billion in 2020 according to Bitkom (2021): “Angriffsziel deutsche Wirtschaft: mehr als 220 Milliarden Euro Schaden pro Jahr“.

to EUR 3.3 billion and EUR 13.0 billion to EUR 21.45 billion respectively.[191] Using the data available for Germany, it is estimated that option 4 b) could lead to an EU-wide reduction in costs stemming from incidents affecting companies by between roughly **EUR 180 billion to EUR 290 billion annually.**[192]

There are no aggregate estimates of the cost of security incidents in Europe. The figures under PO3 and PO4 were calculated using **the cost of security incidents** in Germany as estimated by the German trade association Bitkom. The aggregated cost of security incidents in Germany amounted to EUR 220 billion in 2020 according to Bitkom (2021): "Angriffsziel deutsche Wirtschaft: mehr als 220 Milliarden Euro Schaden pro Jahr". In order to calculate the aggregated benefits in terms of cost savings, the percentage of reduced cybersecurity incidents due to the policy intervention (as foreseen in the related policy option) is applied to the aggregated costs of security incidents in Germany and then extrapolated to the EU.

The aggregate cost of security incidents in Germany amounted to EUR 220 billion in 2020 according to the Bitkom (2021) study *"Angriffsziel deutsche Wirtschaft: mehr als 220 Milliarden Euro Schaden pro Jahr"*. The data is based on a survey conducted by Bitkom Research on behalf of the digital association Bitkom. It surveyed 1 067 companies with 10 or more employees. The interviews were conducted with executives who are responsible for the topic of business protection in their company. These included managing directors and executives from the areas of corporate security, IT security, risk management or finance. The survey is representative of the economy as a whole. The study found out that nine out of ten companies (88 percent) were affected by attacks in 2020/2021 (compared to three quarters (75 percent) in 2018/2019).

The table below summarises the estimations of all companies surveyed in the context of the Bitkom study that were affected in the last 12 months (prior to 2021: in the last 2 years) by theft, industrial espionage or sabotage (2021: n=935; 2019: n=801; 2017: n=571; 2015: n=550). These figures indicate direct and indirect sources of costs. For the purpose of this report, the assumption is taken that the theft, industrial espionage or sabotage impacting the German industry are direct and indirect consequences of cybersecurity incidents. For these reasons, using this figure will likely lead to an overestimation of cost savings for businesses due to reduced cybersecurity incidents.

Causes of damage	Loss amounts in billions of euros (2021)
Failure, theft, or damage of Information and production systems or operations	61.9
Extortion with stolen data or encrypted data	24.3
Data protection measures (e.g., informing customers)	17.1
Patent infringements (even before filing)	30.5
Loss of sales due to loss of competitive advantage	29.0
Loss of sales due to counterfeit products (plagiarism)	22.7
Damage to image among customers or suppliers/negative media coverage	12.3
Costs of investigations and substitute measures	13.3
Costs of legal disputes	12.4
Higher employee fluctuation/staff poaching	N.A.
Other losses	2.2
Total	223.5

Sources: https://www.bitkom.org/Presse/Presseinformation/Angriffsziel-deutsche-Wirtschaft-mehr-als-220-Milliarden-Euro-Schaden-pro-Jahr ; Overview of the results of the survey: https://www.bitkom.org/sites/main/files/2021-08/bitkom-slides-wirtschaftsschutz-cybercrime-05-08-2021.pdf

Box 3: German study on economic impacts of security incidents

The upper-bound benefit of EUR 290 billion alone is estimated to be roughly ten times higher than the compliance costs (see *section 8*) and does not even take into account other non-quantifiable benefits, in particular under policy option 4, such as the decrease in risk mitigation costs for users; the higher uptake of digital solutions as a result of an increased trust in modern technologies; the reduction in risk mitigation costs (such as cybersecurity insurance) as a result of the reduction in the overall attack surface of products with digital elements; smaller reputational damage to manufacturers resulting from fewer incidents involving vulnerabilities in their products; enhanced productivity of manufacturers from a security point of view; and prevention of the potential costs

[191] According to the impact assessment of the delegate Radio Equipment Directive, the annual costs of data breaches are at least EUR 10 billion and the annual costs of DDoS are estimated to be at least EUR 65 billion.

[192] There are no aggregate estimates of the cost of security incidents in Europe. The figure was calculated using the cost of cybersecurity incidents in Germany and by extrapolation using the share of German GDP in European Union GDP. The aggregate cost of security incidents in Germany amounted to EUR 220 billion in 2020 according to Bitkom (2021): "Angriffsziel deutsche Wirtschaft: mehr als 220 Milliarden Euro Schaden pro Jahr".

of market fragmentation that manufacturers would be facing if Member States decided to intervene in the market.

The table below presents an overview direct costs and benefits described in this section (and further detailed in the following sections):

	Total direct compliance costs	**Benefits (direct and indirect)**
PO 1		
	Depending on the uptake of voluntary measures: • Secure product development costs (+30.5%) • EU certification (EUR 25 000 - 40 000)	Depending on the uptake of the voluntary measures: • Reduced cybersecurity incidents for end-users (decrease of vulnerabilities of around 33% by product) • Avoidance of costs related to security risk mitigation (e.g. insurance) for end-users • Increased uptake of products with digital elements by EU users and globally due to a reduction in risk associated with CE marked products with digital elements • Direct cost reduction for manufacturers that already use certification due to harmonisation
PO 2		
Amending sectoral NLF legislation	Secure product development (in average 30.5%	• Similar to PO1 depending on sectoral scope
Amending RED delegated Act	17.5 bn (for software only)	Limited to wireless products: • Reduced cybersecurity incidents for end-users • Reduction of costs and cybersecurity incidents • Increased uptake of products with digital elements in the EU and globally
PO 3		
3(i)	EUR 11.2 bn	• Reduced cybersecurity incidents for end-users (decrease of vulnerabilities of 33% by product): by **roughly EUR 90 bn to EUR 140 bn** • *Limited to the hardware market:* o Avoidance of costs related to security risk mitigation (e.g. insurance) for end-users o Increased uptake of products with digital elements by EU users and globally due to a reduction in risk associated with CE marked products with digital elements
3(ii)	EUR 11.3 bn	
PO 4		
4(a)(i)	EUR 13 bn	• Reduction in costs stemming from incidents affecting companies by roughly **EUR 97 bn to EUR 158 bn** • Avoidance of costs related to security risk mitigation (e.g. insurance) for end-users • Increased uptake of products with digital elements by EU users and globally due to a reduction in risk associated with CE marked products with digital elements
4(a)(ii)	EUR 13.1 bn	
4(b)(i)	EUR 28.8 bn	• Reduction in costs stemming from incidents affecting companies by roughly **EUR 180 billion to EUR 290 bn annually** • Avoidance of costs related to security risk mitigation (e.g. insurance) for end-users • Increased uptake of products with digital elements by EU users and globally due to a reduction in risk associated with CE marked products with digital elements
4(b)(ii)	EUR 29 bn	

Table 7: Overview of aggregated direct costs versus benefits for businesses by policy option 4

6.3.2. Impact on SMEs

SMEs will be significantly impacted by the initiative, both in terms of costs and benefits. They will be directly impacted by the new requirements as economic operators, i.e. as manufacturers, distributors or importers. Regarding manufacturers of products with digital elements, more than 99% are SMEs (see section 5). The share of SME distributors and retailers of products with digital elements could not be estimated. Furthermore, SMEs will be impacted by the initiative as end-users of products with digital elements. SMEs have been significant spenders in technology, with companies with less than 1 000 employees spending more than USD 30 billion a year on software alone.[193]

Policy option 1 is not expected to add significant costs on SMEs, while at the same time, SMEs may engage in voluntary measures to increase their market reputation. In the public consultation, SMEs rated the costs related to voluntary measures (guidelines, certification and public procurement) at respectively 3.4, 3.1 and 2.7 out of 5 (with 5 meaning very costly). Taking into account all organizations representing SMEs, the rating was similar (respectively 2.79; 3.00 and 2.87). European certification would significantly reduce costs and administrative burden for SMEs that already certify or are willing to certify their products and services at various levels of assurance. At the same time, benefits in terms of security for SMEs as end-users would be limited.

Under policy option 2, additional compliance costs would be borne by SMEs covered by the specific product regulation. In the public consultation, SMEs rated the costs with an average of 2.6 out of 5 (with 5 meaning very costly), lower than the average of other stakeholders (3.36). Taking organizations representing SMEs as a whole it was rated at 3.6. Furthermore, SMEs could face the costs of having to comply with multiple product specific legislations (*section 6.4*).

Under policy option 3, additional compliance costs would be borne by SME manufacturers, especially in the hardware segments that are currently not covered by product legislation, but also manufacturers of embedded software. Policy option 4 would in addition add compliance costs on SMEs software manufacturers. In the public consultation, SMEs rated the costs related to policy option 3 and 4 below or similar to the average. *Introducing mandatory horizontal cybersecurity requirements for hardware products* was rated at 3.55 out of 5 by all stakeholders in average (with 5 indicating very costly), while organizations representing SMEs in general rated it higher at 3.54. At the same time SMEs as end-users would benefit from greater legal certainty and more secure products in the hardware sector. SME companies rated the costs related to *Introducing mandatory horizontal cybersecurity requirements for software products*, at 3 out of 5 (the average was 3.68), while organizations representing SMEs rated it slightly higher at 3.59.

SMEs generally supported a level playing field between all companies. To the question on *whether small and medium-sized companies should be subject to the same obligations as larger companies*, organizations representing SMEs responded in average 3.92 out of 5 with 5 indicating that they strongly agree. Furthermore, in the public consultation SMEs did not consider that they would be disadvantaged compared to larger companies in a scenario of horizontal mandatory requirements (policy option 3 and 4). To the question on whether "*Mandatory cybersecurity requirements will put smaller hardware manufacturers and software manufacturers developers at a disadvantage compared with larger competitors*", SME representatives were neutral (2.41 out of 5 with 5 indicating strongly agree). SMEs representatives were also neutral regarding the statement that EU companies are *at a disadvantage on the non-EU markets compared to non-EU competitors that are not subject to such requirements* (2.5 out of 5).

Several SMEs throughout the consultation activities expressed concerns that increasing the cost of development would possibly cause a competitive disadvantage vis-à-vis large companies and third countries. Some also expressed the fear that the compliance costs could not be borne by some SMEs, which might disappear from the market. SME representatives consistently called **for a proportionate approach and for supporting measures**. To the statement on the need to *Introduce simplified procedures to demonstrate conformity for small companies and individual*

[193] nearly half of which is spent on vertical- or industry-specific software, including cloud: https://www.mckinsey.com/industries/technology-media-and-telecommunications/our-insights/reversal-of-fortune-how-european-software-can-play-to-its-strengths

entrepreneurs, organizations representing SMEs replied on average at 2.79 out of 5 (with 5 indicating strongly agreed), while SMEs rated it in average at 3.7 out of 5. SME representatives stressed that SMEs would likely bear higher compliance costs and that these costs should remain proportionate and be reachable for SMEs. At the same time, stakeholders consistently stressed that any differentiation in terms of requirements and testing based on the size of the company should be avoided. Lighter administrative procedures and obligations could follow a risk-based approach and be based on the criticality of the product.

In terms of costs, **SMEs as manufacturers would in principle be more affected than large companies for several reasons**. Larger companies can more easily distribute the one-off costs of familiarising themselves with new regulation. Furthermore, larger companies have typically a larger customer base and can therefore distribute the fixed costs over more customers (economies of scale). Most importantly, SMEs' financial capacity to absorb fixed costs is much more limited.[194] First, SMEs might lack awareness and knowledge about cybersecurity in general,[195] it might therefore be more costly for them to gather the knowledge about new security requirements, and to implement those. Due to limited internal technical and legal expertise, SMEs tend to turn to external consultants, increasing overall costs. Also, due to the limited capacity of their laboratories – as regards both economic resources and competences – SMEs have to use external testing laboratories or notified bodies to ensure compliance with applicable NLF-aligned legislation. According to a national trade association representing SMEs, 61% of SMEs report obstacles in ensuring their cybersecurity, the biggest challenges being inadequate skills and the costs of cybersecurity. According to an ENISA survey, approximately 12.3 % of the SMEs believe that their information security performance is ‘below’ or ‘far below industry standards’, compared to only 2.1 % for the large enterprises.[196] While these figures point to higher additional compliance costs, this also indicates the need to bring the security level of products manufactured by SMEs to an adequate security level.

Regarding policy options 3 (ii), and 4 a) (ii) and (b) (ii), **mandatory third-party assessment could entail considerable costs for SME manufacturer**, as highlighted by several stakeholders in the public consultation. One trade association representing SMEs mentioned that a too extensive scope of products to be covered by third-party assessment could have serious effects on specialised SMEs up to ceasing their activities. At the same time, other stakeholders in the targeted survey[197] mentioned that SMEs might prefer third-party assessment to avoid higher one-off costs for self-assessment. As a result, flexibility in choosing the conformity assessment seems important to offset the costs on SMEs.

It is important to note that not **all SME manufacturers will be impacted in the same way**. Some SMEs reported in the open public consultation and in conducted interviews that some costs could be covered by business as usual costs (e.g. some standards are already in place). Those SMEs that have no security measures in place will be the most impacted. However, it has not been possible to estimate the risks of market fall out due to excessive compliance costs for the SMEs.

SMEs as **importers and distributors** would bear some familiarisation costs, however as stressed by several SMEs representatives, these economic operators will benefit from the fact that "cybersecurity must already be ensured by the manufacturer". Therefore the burden on SME importers and distributors is not expected to be significant, on the contrary.

[194] Estimates for 2018 produced by DIW Econ, based on 2008-2016 figures from the Structural Business Statistics Database, Structural business statistics overview: SMEs produce an average annual value added of EUR 174 000, going as low as €69 000 for micro-enterprises (less than ten employees), compared to €71.6 million for large enterprises.

[195] See also SWD(2021) 302 final, IA accompanying the RED Delegated Act.

[196] https://www.enisa.europa.eu/publications/nis-investments-2021

[197] Targeted survey on impacts launched on 16 May 2022 organised by the study supporting this impact assessment

SMEs as end-users might also face higher initial prices, similar to other end-users (see section 6.2.4). However, these are not expected to be outweighed by the benefits of enhanced security and transparency (see below).

The following elements will help to off-set higher compliance costs for SME manufacturers, in particular under policy options 3 and 4:

- ✓ **Proportionality** of **security requirements and testing methodologies** was mentioned as essential by several SME representatives to avoid undue burden. Such a proportionate approach is foreseen under policy options 3 and 4. The essential cybersecurity requirements in the legislative proposal would be objective-oriented and proportionate building on widely used standards (such as ISO 27000 series and the IEC 62443 series, see *Annex 14*), and the standardisation process that will follow would take into account the technical specificities of the products. This means that for a given risk level, security controls would be adapted. Furthermore, the envisaged horizontal rules would only foresee third-party assessment for high-risk products. This would not represent more than 10% of the markets for products with digital elements. The impact on SMEs would depend on their presence in the market of the specific product categories. Given the risk profile of these products, the BaU costs is expected to be high.
- ✓ Regarding the **proportionality of the costs for conformity assessment**, notified bodies conducting the third party assessments would take the size of the company into account when setting their fees, as it is currently the practice in NLF legislation.[198]
- ✓ Alignment of harmonised standards stemming from the initiative with **European and international standards** was stressed by SME representative as an important factor to reduce compliance cost. As previously mentioned, the EU standardisation process will build on existing standards.
- ✓ SME representatives stressed the need for **support measures**, while maintaining a level playing field between businesses. Such support measures could include the exchange of best practices and information sharing. They would stem from:
  - ➢ ENISA has put in place different tools to provide advice to SMEs in securing their business.[199] Other initiatives are under development, such as to self-assess the security maturity levels of SMEs. EU financial support will contribute to facilitate the implementation of EU regulation on cybersecurity (see *Annex 10*). For instance, EU programmes for research and innovation (Horizon Europe) and for capacity building (Digital Europe) and their respective precursor programmes aim to support EU know-how in security certification (in relation to the Cybersecurity Act) as well as capacity building and training, including for SMEs. The Digital Innovation Hubs funded from Digital Europe and National Coordination Centres under the Cybersecurity Competence Centre and Network regulation are resources for SMEs, which seek technical advice for product development or testing and/or EU cybersecurity financial support. In the 2021-2027 MFF period, Horizon Europe and Digital Europe will invest in the order of EUR 2 billion in a wide variety of cybersecurity topics and actions (see *Annex 10*).

On the other hand, SMEs are expected to benefit from the initiative in several ways, both as manufacturers and end-users, likely even more than large companies. First, as end-users, due to their limited capacities described previously, SMEs are likely to be more impacted by cybersecurity attacks, as evidenced by the open public consultation (OPC).[200] Furthermore, according to an ENISA survey, 90 % of the SMEs stated that cybersecurity issues would have

[198] SWD(2021) 84 final, Impact assessment accompanying the Artifical Intelligence Act.

[199] For instance, ENISA set up an online tool for SMEs (besides tips from ENISA, it also provides links and information from national efforts): https://www.enisa.europa.eu/securesme.

[200] As stated in the problem definition, SMEs and organisations representing SMEs rated the material and reputational impacts of cyber incidents higher than other stakeholders.

serious negative impacts on their business, with **57 %** saying they would most likely become bankrupt or go out of business.[201] Therefore, while embedding security in products with digital elements would present a high compliance costs for some SME manufacturers, it would present significant cost saving for SMEs as end-users. SME as end-users would significantly benefit from enhanced transparency of security properties of products. As stated by a national trade association representing SMEs: "*In our experience, SMEs also often find it difficult to tell secure solutions and vendors from insecure ones due to the lack of transparency of cybersecurity features and standards. The absence of trust creates uncertainty and can result in SMEs holding back their much-needed investments in digitalisation".* As manufacturers, distributors and importers of products with digital elements, SMEs can benefit from larger trust from end-users and therefore possibly gain new customers. Larger companies typically already benefit from an established customer base, and therefore the benefits in terms of reputation could be even higher for smaller companies. A seamless access to the internal market with harmonised security requirements for all products with digital elements accross sectors can be even more beneficial for SMEs, as they are less equipped to handle different regulatory requirements and related compliance costs.

6.3.3. Impacts on public authorities and notified bodies

A horizontal regulatory initiative will impact national authorities such as national accreditation bodies and market surveillance authorities (MSAs), as well as private notified bodies (i.e. notified conformity assessment bodies). These entities have responsibilities related to the monitoring and enforcement of the measures proposed under the different policy options. As the responsibilities of MSAs and notified bodies grow, their capacity to assess products' technical characteristics from a cybersecurity perspective need to be ensured. In this context, the need for appropriate skills (e.g. to assess software products) has been stressed as a key challenge by stakeholders.

Furthermore, next to the usual authorities involved in market surveillance under the NLF, ENISA will take over tasks in particular related to the collection and dissemination of exploited vulnerabilities in view of enhancing intelligence on cybersecurity threats to the internal market.

Direct costs for public authorities and notified bodies

Market surveillance authorities (MSAs)

The main cost sources for MSAs include: (i) possible creation of new authorities (one-off); (ii) familiarisation and training on the new requirements for existing or new authorities (one-off and recurrent for new staff), and (iii) enforcement of the new requirements, including post-market surveillance as part of life cycle approach (one-off and recurrent). In the long-term, cost-savings could occur thanks to a horizontal approach on security requirements (see *section 6.4*). The number of MSAs is still to be confirmed (discretion of Member States) and the precise impact will depend on the choices of Member States for the new MSA to be appointed under options 3 and 4. Different models can be envisaged by Member States in order to ensure that competent authorities would have the required expertise[202].

Under policy option 1, adjustment costs of market surveillance authorities would occur where a new certification or labelling mechanism is introduced. In the case of EU certification, market surveillance authorities already exist, i.e. the national cybersecurity certification authorities, however enforcement costs would occur if new schemes are deployed. When asked on the impact of voluntary measures in the public consultation, market surveillance authorities overall rated this option as **"very low"** (1/5 with 5 indicating very costly).

Under policy option 2, MSAs appointed under existing product legislation will need to adjust to additional requirements that include cybersecurity. On a case-by-case basis, additional resources will be required for enforcing new cybersecurity requirements on hardware products (e.g.

[201] https://www.enisa.europa.eu/topics/national-cyber-security-strategies/sme_cybersecurity

[202] *Final Report, Supporting Study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008), March 2022) - page 64 and 65*

additional physical checks of the products' technical characteristics and of the technical documentation against the minimum baseline security requirements). When asked in the public consultation on the costs of amending product specific legislation, public authorities acting as market surveillance authorities rated them **"high"** (4 out of 5 with 5 indicating very costly).

Under policy options 3 and 4, additional adjustment and enforcement costs would occur. The market surveillance authorities will be appointed by Member States and can differ from one Member State to another. The precise compliance and enforcement costs are thus difficult to estimate. When asked in the public consultation about the costs of horizontal legislation, public authorities acting as market surveillance authorities rated them **"high"** (4 out of 5 with 5 = very costly).

In the context of the Cybersecurity Act,[203] it was estimated that Member States appointing a competent certification authority are expected to bear costs that would approximately amount to EUR 1 600 000 per year. This estimate includes costs related to personnel, equipment, subcontracting, operations as well as setting up of evaluation facilities. However, it is expected that most Member States would appoint existing authorities under policy options 3 and 4.

In order to estimate the enforcement costs, secondary data was used from the impact assessment of the delegated act of the RED[204]. MSAs stated that their estimated costs for enforcing the new (cybersecurity) requirements would be in the order of EUR 5 000 – EUR 10 000 for each type of simple equipment, and up to EUR 20 000 for each type of more complex equipment. In order to aggregate the costs, an **average costs by product of EUR 12 500** is estimated, and the number of products is estimated based on the ICT-EXT-ADJ and SD market indicators. Under policy option 3, the enforcement costs are likely to be lower when third-party assessment is implemented as market surveillance is carried out to some extent by notified bodies, however this difference could not be captured in the cost estimates. Hence, in average, under policy option 3 i) and ii), **aggregated enforcement costs for MSAs** are estimated of **EUR 3.1 billion**.

Under policy option 4, the enforcement costs would increase due to the broadened scope of products compared to policy option 3. As for policy option 3, the difference related to mandatory third-party assessment could not be captured. Under policy options 4 a) i) and ii), assuming that critical software represents 10% of the software market, the aggregated enforcement costs can be estimated at **EUR 3.6 billion**. Under policy options 4 b) i) and ii), the aggregated costs could be estimated at **EUR 7.7 billion**.

ENISA, the EU Agency for Cybersecurity

Under both policy option 3 and 4 and their respective sub-options, ENISA is tasked to receive notifications from manufacturers of actively exploited vulnerabilities contained in the products with digital elements, as well as incidents having an impact on the security of these products. Cost sources for ENISA would stem from collecting the information, from the preparation of intelligence on emerging trends regarding cybersecurity risks in products with digital elements to the national competent authorities and the European Commission, e.g in the NIS2 Cooperation Group, as well as from providing advice to support the implementation process of this Regulation. Such activities will involve additional adjustment costs for ENISA.

Drawing on the impact assessment of the NIS2 Directive[205], under option 4 b), collecting and disseminating information on exploited vulnerabilites to competent authorities could be estimated to require 3 FTEs. Any structured reporting and advice on the implementation of the initiative could add 1.5 additional FTEs. Taking into account the scope of the respective policy options, this amount could approximately be reduced to 2.5 FTE under option 3, and 3.5 FTEs under option

[203] SWD(2017) 500 final, IA accompanying the Cybersecurity Act.

[204] *Final report for RED Delegated Act Impact Assessment*, page 140

[205] https://digital-strategy.ec.europa.eu/en/library/impact-assessment-proposal-directive-measures-high-common-level-cybersecurity-across-union

4a). These administrative costs would however be offset by reduced activities linked to the implementation of the European cybersecurity certification framework (as described in the policy options 3 and 4 in *Section 5*), and therefore would amount to budget re-allocation.

	Costs
PO 1	neutral/+
PO 2	++
Amending sectoral NLF legislation	
Amending RED delegated Act	*Aggregated enforcement costs for MSAs: EUR 4.6 bn
PO 3	
3(i)	*Aggregated enforcement costs for MSAs: EUR 3.1 bn * Vulnerability reporting for ENISA: 2.5 FTEs
3(ii)	
PO 4	
4(a)(i)	*Aggregated enforcement costs for MSAs: **EUR 3.6 bn** - EUR 12 500 additional costs by new product *Vulnerability reporting for ENISA: 3.5 FTEs
4(a)(ii)	
4(b)(i)	*Aggregated enforcement costs for MSAs: **EUR 7.7 bn** - EUR 12 500 additional costs by new product * Vulnerability reporting for ENISA: 4.5 FTEs
4(b)(ii)	

Table 8: Overview of aggregated costs for public authorities by policy option

National accreditation authorities and notifying authorities

The main impacts for accreditation and notifying authorities will be linked to additional adjustment (e.g. additional training and human resources) and enforcement costs to take into account the new requirements. The resources spent by accreditation bodies in relation to NLF implementation are however **offset and borne largely by conformity assessment bodies through the purchase of accreditation services.** It is difficult to estimate the costs on national accreditation authorities and notifying authorities given their differences between Member States and their specificities (e.g. some are publicly funded, others private).

Under policy option 1, additional adjustment and enforcement costs for accreditation authorities would occur if a new European certification or labelling scheme is introduced. Under policy option 2, accreditation and notifying authorities would already be in place, but would bear adjustment and enforcement costs for accrediting conformity assessment bodies for cybersecurity requirements. Under policy options 3(i) and 4(i), self-assessment would be the rule, while third-party assessment would be optional for economic operators. Accreditation authorities will need to accredit notified bodies competent under the new legislation. This would lead to additional adjustment and enforcement costs, which would be mainly offset by fees paid by notified bodies. These costs are expected to increase with the extension of scope to non-embedded software (option 4) and if third-party assessment is mandatory (option 4 (ii)).

Notified bodies

Bodies that have been notified by the accreditation or notifying authority of a Member State have a key role in verifying the security and the compliance of products placed on the market. Notified bodies will mainly bear adjustment costs (e.g. training and new staff) and charges linked to the implementation of the new accreditation framework. These costs are both one-off (examination fee) and recurrent (annual fee to accreditation body and costs to develop a quality management system). The costs will partly depend on the processes in place and the availability of resources of the notified body. Fees will also differ depending on the accreditation body. In the context of the Commission evaluation of the NLF, the examination fee for accrediting a body, a one-off cost, was estimated between EUR 4 000 and EUR 20 000 per accreditation.[206]

[206] Draft European Commission (2022) Staff Working Document "Evaluation of the New Legislative Framework", Part 2/2 [to be published].

Under policy options 2, 3, and 4, notified bodies will bear one-off and recurrent costs for adapting to expected changes. On an aggregated level, these will be more important under policy option 3 compared to option 2, and under policy option 4 compared to option 3

Benefits for public authorities and notified bodies

Policy option 1 and policy option 2 will have limited impacts for MSAs, accreditation bodies, national notifying authorities in terms of preventing internal market fragmentation (*section 6.5*). Furthermore, under these policy options, public authorities in general would have limited benefits in terms of security of products with digital elements (*section 6.3.4* and *section 6.6*).

Under policy option 3 and 4, MSAs, accreditation bodies and national notifying authorities will benefit from the internal market effect of a horizontal intervention: harmonised security requirements for a wide range of products with digital elements instead of dealing with multiple national and/or European product legislation (see *section 6.5*). In addition, for accreditation bodies and national notifying authorities, costs will be offset by fees paid by notified bodies. While notified bodies will bear compliance costs, they will also benefit from an internal market effect. Furthermore, they will be remunerated for their conformity assessment services. In the context of the review of the Machinery Directive, increased turnover due to third-party assessment was estimated at EUR 202 million.[207] Public authorities in general will benefit as end-users from enhanced transparency on security properties and on secure use of products with digital elements and reduced compliance costs to meet other EU and national cyber relevant legislation (e.g. NIS) (*section 6.3.4*). They will also benefit from reduced cyber incidents and cyber mitigation costs (*section 6.6.*).

In addition, the burden on public authorities and notified bodies can be **partly offset by EU financial programmes** that have supported in the past MSAs, accreditation and notified bodies to facilitate the implementation of EU regulation on cybersecurity, and will continue to do so in the future (see *Annex 10*). As for SMEs (*section 6.3.2.*), EU programmes for research and innovation (Horizon Europe) and for capacity building (Digital Europe) and their respective precursor programmes support know-how in security certification (in relation to the Cybersecurity Act) and in relation to capacity building and training for competent authorities under the NIS Directive. In the same vein, and in order to partially offset potential costs related to the implementation of horizontal cybersecurity legislation, EU financial support will, subject to the respective programme governance decisions, support capacity building for public authorities and notified bodies. For a detailed overview, see *Annex 10.*

6.3.4. Impact on users: organisations, citizens and consumers

As described in *section 6.6.*, the mandatory security requirements for products with digital elements would lead to an increase in the security of hardware and software products, lowering the **risk of cybersecurity incidents** for both organisations (businesses and public administrations) and consumers as well as the customers of services that would be affected by fewer security incidents, such as data leaks. This would be in **particular beneficial to SMEs**, as several respondents to the public consultation pointed out that the negative impacts of cybersecurity incidents are more prominent for SMEs. Moreover, requiring manufacturers to document the security properties of their products would help users to make better purchasing decisions, allowing them to compare products-based security properties and individual security needs. While many users lack the necessary skills to analyse such information, it is very likely that consumer protection organisations, computer magazines, security consultants and other market actors would use this information to help users make informed choices. Similarly, requiring manufacturers to provide instructions on how to use products securely would empower users and ensure a more secure deployment of products.

[207] SWD(2021) 82 final, IA accompanying the Machinery Regulation: based on the difference in cost for conformity assessment of third-party assessments compared to internal checks for 10% of products that currently undergo internal checks (Annex IV).

As regards the impact on **risk mitigation costs** that businesses are facing, the measures are expected to lead to a decrease in such costs: business users could more confidently rely on the security of products with digital elements, knowing that the products have undergone a conformity assessment. According to a recent study by Gartner of behalf of ENISA, the initiative would have a very positive impact on key operators required to take cybersecurity measures under the NIS Directive: 55 % of operators of essential services consider that the intervention would lead to a reduction in risk mitigation costs (i.e. cybersecurity investment).[208]

As described in *section 2.1*, users forgoing investment in products with digital elements is one of the consequences of the low level of security provided by products with digital elements. With users and in particular businesses becoming more confident in the security of products with digital elements, the initiative would therefore also lead to an increased **uptake in digital solutions**.

As regards business users, the initiative would lower the **compliance costs with existing legal acts**, such as the NIS Directive or the GDPR, in particular when it comes to supply chain security requirements: In the aforementioned Gartner study, 71 % of operators of essential services consider that the intervention would lead to a reduction in supply chain security compliance costs.[209]

Finally, as the manufacturers of products with digital elements will be facing compliance costs to implement cybersecurity requirements, they are likely to pass on some of these costs to users, leading to an **increase in prices** for consumers as well as organisations. However, this is not expected to have a significant impact. When asked in the public consultation whether they *valued products' usability and price over cyber security features*, 46 % of respondents disagreed and only 12 % seemed to privilege usability and price over cyber security. The results were similar for SMEs.[210] Based on the impact assessment of the RED delegated act, for lawnmowers, the additional costs for end-users could be up to 3 EUR per unit more expensive compared with a non-secured lawnmower product with cheap Wi-Fi connectivity. Integrated encryption into the Central Processing Unit (CPU) would require changes to the electronics and additional technical support, which could result in extra costs to the end-user of up to 10 EUR per unit. The price increase per router for testing would be up to EUR 0.355 per device.

In addition, transparency requirements would contribute to boosting the awareness of users of the security risks associated with certain products. Consumer protections organisations and other actors, such as security researchers or computer magazines, could use the additional information provided by manufacturers to provide consumers and organisational users with a better overview of the security properties and features of products with digital elements, helping them make better purchasing and deployment decisions.

Under policy option 1, the positive impact on users in terms of security, risk mitigation, digital uptake and compliance costs would be limited, considering that no mandatory measures would be imposed. However, additional certification schemes could incentives certain players to undergo ICT product certification, boosting confidence of users in such products and lowering businesses' compliance costs with other legislation. Under policy option 2, there would be a positive impact on users for a limited number of products covered by the NLF legislation. However, the majority of products with digital elements in the EU are currently not covered by any NLF legislation. A more substantial impact would occur if the scope if the RED Delegated Act is extended to non-emebedded software. Under policy option 3, which includes a horizontal regulatory intervention for a broad scope of tangible products with digital elements, the positive impact on users in terms of security, risk mitigation, digital uptake and compliance costs would increase dramatically as

[208] Calculation based on the preliminary results of a still ongoing survey commissioned by ENISA and executed by Gartner (2022): NIS Investments Study 2022.

[209] See previous footnote.

[210] Medium companies were mostly neutral (43%) and disagreed (47%); small companies disagreed (42%), were neutral (33%), but also partially agreed (17%); micro companies tended to disagree (30%) or be neutral (40%).

regards tangible products. It would however remain very limited as regards software products. Under policy option 4, all manufacturers of tangible and intangible products would be expected to take cybersecurity measures, which would lead to a substantial positive impact on users, citizens and consumers in terms of security, risk mitigation, digital uptake and compliance costs with other legislation. In the public consultation, when asked whether *Horizontal cybersecurity requirements for products with digital elements would increase awareness of users when it comes to cyber risks,* 82.22 % of respondents (strongly) agreed.

6.3. Functioning of the internal market

The impact on the internal market depends on how effective the regulatory framework is in preventing the emergence of obstacles and fragmentation by mutually contradicting national initiatives aiming to address the problems set out in *section 2.1*.

Member States are increasingly recognising the need to address concerns regarding the security of products with digital elements. For example, in 2019, Finland has created a labelling scheme for IoT devices, such as smart TVs, smartphones and toys based on the ETSI standards.[211] Germany has recently introduced a consumer security label for broadband routers, smart TVs, cameras, speakers, toys, as well as cleaning and gardening robots.[212] Policy options 1 and 2 explicitly point to the creation of additional voluntary national schemes absent Union legislation.

So far, mandatory national cybersecurity requirements for products with digital elements are rather the exception than the rule in the Member States. One notable example is the mandatory protection profiles introduced by Germany for manufacturers of smart meter gateways.[213] Given the dire state of product security in the internal market, Member States are expected to sooner or later consider further national product rules to protect their critical infrastructure, crucial manufacturing processes or citizens. Such a national approach would inevitably lead to a fragmentation of the internal market.

Most products with digital elements markets are European if not global. Major operating systems, such as Microsoft Windows or Android with its various forks, are sold to a global user base. Similarly, given the importance of economies of scale in hardware markets as described in *section 2.2.5*, many components, such as CPUs or network chipsets, are equally marketed across the globe. For example, infected IoT devices in the internal market can be traced back to the same manufacturers, irrespective of in which Member State they are deployed.[214] National rules on such products would therefore force manufacturers to adjust their products to national markets, resulting in a decrease in cost-effectiveness across the internal market. In some cases, manufacturers, and in particular smaller ones, may even decide not to market a product in regions with a low expected sales volume in order to avoid the additional cost associated with adjusting the product to national rules.

While policy options 1 and 2 may entail additional voluntary national schemes as one way of addressing the problem of low product security, nothing would prevent the Member States from setting their own rules with the negative consequences described above. In the public consultation, when discussing the impacts, multiple stakeholders expressed the dangers of legislative fragmentation, and mentioned that any interventions that foster fragmentation (voluntary vertical schemes or national regulatory schemes) will drive significant compliance costs and complexity to no improved security. Under policy option 2, internal market fragmentation could at least be prevented for those products that are regulated under the NLF. However, in the public consultation, several stakeholders mentioned that amending different legislation with cybersecurity

[211] ETSI EN 303 645 standard. Traficom (2019).

[212] BSI (2022).

[213] German Metering Point Operation Law ("Messstellenbetriebsgesetz", MsbG), §22.

[214] Rodríguez et al (2021): "Superspreaders: Quantifying the Role of IoT Manufacturers in Device Infections", *20th Annual Workshop on the Economics of Information Security (WEIS 2021)*, for a more detailed discussion of IoT consumer device security, p. 8.

requirements would lead to a multiplicity of non-homogeneous requirements and increase the overall cost. Policy option 3 would effectively prevent internal market fragmentation for all tangible products, given its horizontal regulatory intervention in this area. Given its staggered approach to the introduction of security requirements for non-tangible products, internal market fragmentation in the area of software would most likely be temporary. Policy option 4 would be the most effective in preventing fragmentation, as the horizontal regulatory intervention would cover a broad scope, including all software. In the public consultation, to the question whether "*Horizontal cybersecurity requirement would improve the functioning of the internal market by levelling the playing field for manufacturers […]*", over 88 % respondents strongly agreed.

6.4. Competitiveness, innovation and trade: Impacts on EU and non-EU companies

Competitiveness and trade in the software and hardware markets

Competition in the software market is generally global and the sector is a highly profitable one. Software is used to a large extent from external providers, either as a ready-to-use system or via hired external contractors. Therefore, companies from outside the EU find it relatively easy to win customers, and as a result supply chains are often international. The EU is importing more than exporting software products. In percentage terms, the software share of extra-EU exports is separated from that of intra-EU27 imports by **18 %** (see *Annex 3*).

Regarding hardware, EU imports from third countries and intra-EU imports are similar shares, with intra-EU imports only surpassing extra-EU ones by five percentage points. The competitiveness of EU products and commercial balance might vary from one sub-category of hardware product to another. In 2021, several product categories that are amongst the top EU export products could be covered by a possible horizontal regulatory intervention such as: machinery and equipment (12.9 % of total exports), and computer, electronic and optical products (7.9 %).[215] Amongst the top EU imports are: computer, electronic and optical products (14 % of total imports); machinery & equipment, electrical equipment and basic metals (all three 6 %).

Possible impacts on EU and non-EU companies in terms of competitiveness

Regarding the impact on **EU companies**, on the one hand, additional compliance costs could increase the development and production costs of EU companies and hence their ability to export products globally. Furthermore, conformity assessment might delay the placing on the market of a product with digital elements, and hence the first mover advantage. On the other hand, the initiative can impact positively the uptake of products with digital elements globally and enhance the productivity and reputation of European companies from a security standpoint, thereby contributing to Europe's position as global leader in cyber-secure products.

Under policy options 1 and 2, the impact on Europe's competitiveness would be limited, both in terms of possible compliance costs and benefits. Given the voluntary nature of the measures, the impact of these options on reputation is expected to be limited to those manufacturer that decide to engage into voluntary measures, such as national labelling and EU certification. The absence of any "CE mark" or alike for a substantial part of the hardware and software market will however reduce the impact on enhancing the reputation and visibility of EU products with digital elements globally (and similarly, non-EU products with digital elements offered on the EU market). The increased demand for products with digital elements would depend on the extent to which voluntary measures penetrate the market.

Under policy option 3, and policy option 4, additional compliance costs would occur respectively for European and non-EU hardware and embedded software manufacturers as well as non-embedded software manufacturers. However, it is expected that these policy options would equally strengthen the visibility and reputation of EU hardware and if applicable software products globally as well as of non-EU hardware products on the EU market in terms of cybersecurity

[215] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Main_goods_in_extra-EU_exports

When asked in the public consultation on whether *Mandatory cybersecurity requirements will put EU manufacturers at a disadvantage on the non-EU markets compared to non-EU competitors that are not subject to such requirements,* hardware manufacturers were neutral (2.6 out of 5, with 5 indicating strong agreement), while software manufacturers generally agreed (3 out of 5). Organisations representing SMEs had a neutral stance (2.5 out of 5), and SME companies generally disagreed (2 out of 5). This suggests that software manufacturers could be slightly more concerned regarding the impact on their global competitiveness. In this context, mention should be made that the responses of software developers must be analysed in a wider context, considering that, unlike hardware manufacturers, they have been very limitedly exposed to NLF-type legislation, if at all. Stakeholders stressed the concern that horizontal requirements could undermine the winner-takes-all dynamic, which is by nature even more prevalent in the software sector (or first mover advantage). In particular, third-party assessment under option 4(ii) can delay the timing of placing an EU software product on the global market. However, these impacts are not expected to be significant as only very limited categories of products would be affected by such third-party testing. When asked in the online targeted survey on whether policy option 4 would *negatively affect exports of products with digital elements at industry level*, respondents mentioned a low impact (2.4 out of 10 with 1 being the lowest and 10 the highest). Respondents rated the *negative impact on imports* slightly higher, but still not significant (3.7 out of 10). Furthermore, both under option 3(ii) and 4(a)(ii) and 4(b)(ii), third party assessment could only apply to a very narrow share of products (max. 10%), for which the BaU cost are likely to be high.

A horizontal initiative under policy option 3 and 4 can be beneficial to the European industry, as it would raise the overall security culture in Europe, making European products with digital elements more secure, reliable and trustworthy, and hence competitive. The demand for products with digital elements will continue and/or might even increase on the EU market, and security is an increasing driver of this demand. Hence, a horizontal initiative could contribute positively to build Europe's global technology leadership in the hardware and software market. Assurance on security requirement are both attractive in the B2B sector and B2C sectors.[216]Furthermore, as highlighted in the Commission's sector inquiry on Internet of Things[217] cybersecurity is a key parameter on which consumer IoT manufacturers compete.[218] Experts also highlight that growth for European companies in the software could result by exploiting the competitiveness of the European software industry in the vertical industrial sectors and B2B segment.[219] In this context, assurance on security could provide a competitive strength to European B2B software products in a large number of sectors. Similar to other NLF legislations, a horizontal regulatory intervention is expected to enhance the quality and reputation of "CE marked" hardware and software offered on global markets, and therefore bring competitive strength to European manufacturers compared to their third country counterparts.[220]

A horizontal initiative will have positive effects on innovation in cybersecurity technologies in Europe and boost the competitiveness of European industry. The introduction of security

[216] https://ec.europa.eu/competition-policy/system/files/2022-01/internet-of-things_final_report_2022_staff_working_document_0.pdf

[217] https://ec.europa.eu/competition-policy/system/files/2022-01/internet-of-things_final_report_2022_staff_working_document_0.pdf

[218] See paragraph 114: Manufacturers of smart home devices indicate that the quality, cybersecurity, brand reputation and privacy policy of their own devices play a crucial role when competing with other smart home devices for integration with other devices, services, voice assistants and other smart home user interfaces.

[219] The annual global market for vertical software, which powers industry-specific processes, currently stands at around USD 100 billion and is expected to grow at an annual rate of some 19 % over the next five years: https://www.mckinsey.com/industries/technology-media-and-telecommunications/our-insights/reversal-of-fortune-how-european-software-can-play-to-its-strengths

[220] "According to evaluations of certain NLF legislation, such as the Lifts Directive evaluation, the CE marking is increasingly perceived as a standard of quality by industry beyond EU borders: buyers in Asia and the US are reported to prefer products with a CE marking; also, the harmonised regulatory framework has reportedly helped companies implement a stronger internationalisation strategy in third countries. The EMCD evaluation reached similar conclusions." Final Report, *Supporting Study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)*, March 2022

requirements, such as security by design, as well as conformity assessment, as well as the definition of related harmonised standards (or if applicable, specifications by the Commission) will provide legal certainty for investments and boost the demand for a variety of cybersecurity tools, such pen testing, automatic scanning, etc. Those technologies have been identified as priorities for investments in R&D under Horizon Europe (see *Annex 10).* At the same time, as regards the effects on innovation in general, the intervention would be proportionate and would introduce objective-based requirements, technology and product/sector-neutral, without being overly-prescriptive. A reasonable transition period of 2-2.5 years to prepare the implementation would also be provided (see standardisation below), giving time to the relevant markets to prepare, while providing a clear direction for R&D investments.

The **impact on non-European companies** will be similar to the one on European companies. Given its large share of imports, the EU is an attractive market for non-EU companies. Therefore, exporting to Europe will likely remain attractive for non-EU companies. While it cannot be excluded that some firms might direct their offering to other markets, this effect is not expected to be significant. Furthermore, the initiative could enhance the reputation of non-EU providers on the EU market by demonstrating that they are meeting high security standards. A significant cost could stem from the obligation to have an economic operator established in the Union, which exists in some NLF legislation. However, this is not envisaged in any of the policy options. Last, it is important to stress that while European horizontal requirements for products with digital elements would be the first comprehensive product security initiative globally, EU trading partners, with the US in the lead, are pursuing similar objectives to the EU with regard to security of products with digital elements and have started to introduce measures to address particularly the security of supply chain and security of products with digital elements. (see *Annex 6*).

The role of standardisation in competitiveness and innovation

Under the policy options (3) and (4), following the adoption of the legislation, the Commission will prepare a **standardisation request** (under Regulation 1025/2012 on European standardisation) to the relevant **European standardisation bodies** (ESOs), ETSI and CEN-CENELEC[221], taking account of a transition period from entry into force to application of at least two years to allow the preparation of implementation, including the development of needed harmonised standards by ESOs.

Stakeholders consistently stressed that both EU and non-EU companies that are operating globally would greatly benefit in terms of competitiveness if EU standards and conformity assessment methodologies are as much as possible **aligned with existing European and international standards**. For global (EU and non-EU companies), possible costs could stem from regulatory divergence between the EU and global trade partners. The costs of third party conformity assessment and certification could risk being duplicated across different regulatory jurisdictions if EU rules diverge from each other and from international ones.

The ESOs pointed out that the cost of developing standards is financed primarily by industry (93-95%) followed by national governments (around 3-5%) and the European Commission / EFTA contribution (around 2%)[222]. The approximate cost of creating one standard from scratch was estimated at approximately **EUR 1 million**. The cost is financed primarily by industry (93-95%) followed by national governments (around 3-5%) and the European Commission / EFTA contribution (around 2%)[223]. Compliance with harmonised standards is not mandatory, but creates a presumption of compliance with the legal requirements, unless otherwise specifically provided by the horizontal regulation. This creates a strong incentive for industry to contribute to the

[221] These European standardisation bodies have also been recognised as competent in the context of the RED delegated act.

[222] Final Report, *Supporting Study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)*, March 2022

[223] Final Report, *Supporting Study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)*, March 2022

standardisation work, which is always a voluntary process. The fact that industry bears most of the cost of the system, together with the voluntary character of standards, reflects its high interest in the role of standards, including in support to the application of NLF-aligned legislation. If developed in a timely manner, harmonised European standards can provide a key competitive advantage for European industry by adopting more advanced standards compared to their competitors.

However, it has to be noted that, recently, economic operators and business associations mentioned the development of harmonised standards as a severe issue, generating significant costs for companies beyond the costs associated with the development of standards detailed above. Companies face difficulties in using new standards, reportedly due to delays in the mandates by the Commission and the citation of harmonised standards at EU level: this ultimately hampers companies' competitiveness, as competitors on the global stage (for instance, in the United States and China) adopt more advanced standards than Europe[224].

The alignment with existing and international standards would be ensured in the following ways:

- ✓ The Commission will request the harmonised standards to be developed on the basis of the European horizontal regulation will take account (e.g. through a gap analysis) existing international standards and all other relevant standards developed by that time, including those on the basis of the RED delegated act[225]. The envisaged requirements for the proposal for a horizontal regulation should take into account of the main elements of the standardisation request to be issued on the basis of the RED delegated act.
- ✓ In order to ensure alignment with existing cybersecurity standards, ENISA should be involved in the standardisation work.
- ✓ The adoption of harmonised European standards does not mean that new standards need to be built from scratch. An existing standard can be designated as harmonised standard for presumption of compliance with essential requirements defined in the Union legislation. While there are existing standards related to the security of products with digital elements (see table in *Annex 13*), only a detailed gap analysis would enable to conclude if some standards would provide the required level of security.
- ✓ The EU has already announced the willingness to work closely with its main trading partners, in particular the US to deepen its cooperation "on new cybersecurity technologies and standards".[226]

6.5. Security and resilience

While there is little systematic research measuring the effect of a Security Development Lifecycle (SDLC) on product security, available evidence suggests that firms can significantly reduce the attack surface of their products by implementing a systematic approach to cybersecurity in their development processes. For instance, after introducing its SDLC in 2004, Microsoft was able to reduce the number of critical vulnerabilities in its product range by 66 %.[227]

As regards securing products across the entire life cycle, in particular by providing timely security updates for critical vulnerabilities, Google's Project Zero provides evidence that manufactures can indeed provide security updates much more quickly than under the status quo, if provided with proper incentives. Amongst the software projects that Project Zero is analysing, the number of days between the discovery of a vulnerability and the provision of a fix has dropped from an

[224] Final Report, *Supporting Study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)*, March 2022

[225] See EC standardisation request for RED delegated act: https://ec.europa.eu/docsroom/documents/48359

[226] https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_22_2007

[227] Fonseca and Vieira (2013): "A Survey on Secure Software Development Lifecycles", *Software Development Techniques for Constructive Information Systems Design*, p. 12.

average of 80 days to 52 days.[228] A legally binding requirement covering the entire hardware and software market would produce strong incentives to reduce the time for providing security updates.

Information regarding the actual implementation of SDLC by hardware and software manufacturers is patchy. According to a 2010 survey conducted amongst 46 manufacturers, only 30.4 % of them have implemented a formalised approach.[229] More recent studies focusing on Europe, produce similar findings: A survey of Norwegian public organisations involved in developing software concludes that on average only 39 % of the security measures described in the Building Security In Maturity Model (BSIMM) are implemented.[230] In a 2021 study amongst 61 Finnish software practitioners, 29 % of respondents said their firms were not following any systematic approach.[231] Based on this data, it is estimated that currently less than 50 % of manufacturers have a systematic approach to product development.

Given the low uptake of secure coding practices by manufactures, the introduction of mandatory requirements as regards the security of products and development processes would lead to a significant increase in product security and, as a result, in the security and resilience of users, including critical infrastructures, other providers of essential services and consumers. A survey conducted as part of the NIS Investments Study 2022 shows that developing more secure products and patching holes in existing products would substantially lower the costs associated with cybersecurity incidents: 69 % of critical infrastructure providers and other operators of essential services stated that mandatory cybersecurity requirements for products with digital elements would lead to a reduction in the number of security incidents, suggesting that the intervention would significantly contribute to raising the level of resilience of the most critical parts of the European economy.[232]

Experience has shown that mandatory security requirements are indeed effective in making companies take security more seriously and ultimately in raising the overall level of security. In a 2020 survey assessing the impact of the NIS Directive on security, 82 % of operators of essential services gave the Directive a mark of 4 or above (on a scale from 1 to 5).[233]

Under policy option 1, the number of hardware and software manufacturers that would introduce a SDLC and provide security updates throughout a product's life cycle is unlikely to increase, considering that the additional guidance provided by the Commission would be just one more non-binding recommendation.[234] Under policy option 2, the number could only increase for manufacturers of products covered by NLF legislation and possibly very limited categories of non-embedded software products. Policy option 2 would therefore not provide any additional security for a wide range of critical products, and in particular for non-embedded software, which would remain largely unregulated from a security standpoint. Under policy option 3, the number would increase dramatically for manufacturers of tangible products, as manufacturers would only be able to meet the requirements laid down by the EU horizontal rules by implementing a formalised approach to product security. As regards software manufacturers, they might eventually be required to take a systematic approach to security too (staggered approach). Under policy option

[228] https://googleprojectzero.blogspot.com/2022/02/a-walk-through-project-zero-metrics.html.

[229] E.g. Microsoft's Security Development Lifecycle or the Comprehensive, Lightweight Application Security Process (CLASP): Geer, D. (2010), p. 12-16.

[230] Martin Gilje Jaatun et al (2015): "Software Security Maturity in Public Organisations", *ISC 2015: Proceedings of the 18th International Conference on Information Security - Volume 9290, September 2015*, p. 120-138.

[231] Kalle Rindell et al (2021): "Security in agile software development: A practitioner survey", *Information and Software Technology Volume 131, March 2021, 106488*.

[232] Calculation based on the preliminary results of a still ongoing survey commissioned by ENISA and executed by Gartner (2022): NIS Investments Study 2022.

[233] ENISA (2020): "NIS Investments Report 2020", p. 34, https://www.enisa.europa.eu/publications/nis-investments/.

[234] In addition to existing international standards, such as IEC 6244, which addresses cybersecurity for operational technology in automation and control systems, or ETSI TS 103 732, a protection profile for consumer mobile devices, a number of guidance documents has been developed by industry, such as Microsoft's Security Development Lifecycle. For a comprehensive list of guidance documents, see Yasemin Acar et al (2017): "Developers Need Support, Too: A Survey of Security Advice for Software Developers", *2017 IEEE Cybersecurity Development*, p. 24.

4 b), all manufacturers of tangible and intangible products across the entire supply chain would be expected to take a systematic approach, which should lead to a substantial increase in product security, as manufacturers would not only need to take the security of processes and products seriously before the placing on the market, but they would also have to introduce adequate vulnerability management measures, provide security updates beyond the placing on the market and make information available to users helping them to choose the products with the best security properties and use these products in a secure way. These measures would be entirely absent from policy option 1 and only apply to a limited range of products under policy options 2 and 3. In the public consultation, regarding the question whether *Horizontal cybersecurity requirements for products with digital elements would enhance and ensure a consistently high level of the security of products with digital elements,* over 90 % of the respondents (strongly) agreed.

6.6. Impacts on fundamental rights

All policy options are expected to enhance to a certain extent the protection of **fundamental rights** and freedoms such as privacy, protection of personal data, conduct of business and property or personal dignity and integrity. Policy options 3 and 4 consisting of horizontal regulatory interventions are nevertheless expected to be more likely to help decrease the number and severity of incidents, including personal data breaches. In particular, policy option 4 covering the broadest scope, including all software would be the most effective in this regard.

The horizontal cybersecurity requirements would contribute to the security of personal data by protecting the confidentiality, integrity and availability of information in products with digital elements. Compliance with those requirements will facilitate compliance with the requirement of security of processing of personal data under the GDPR. Certain requirements, such as security by design and default, will also contribute to making the products more data-protection and privacy-friendly from the design phase. A horizontal intervention, and notably the most comprehensive in scope, i.e. option 4 b), would enhance the transparency and information to users, including those that might be less equipped with cybersecurity skills. Users would also be better informed about the risks, capabilities and limitations of the products with digital elements, which would place them in a better position to take the necessary preventive and mitigating measures to reduce the residual risks.

At the same time, the significance of the impacts on the protection of fundamental rights will depend on the degree of regulatory intervention, as presented below.

Respondents to the open public consultation have rated the actual impact of a damage to fundamental rights caused by a cybersecurity incidents affecting products with digital elements as moderate to high, with an overall average rating of 3.8 (on a scale of 1 to 5), a 4.16 rating by users and 4.5 by consumer organisations. SME companies gave an overall rating of 4.

As regards the overall impact of cybersecurity requirements on fundamental rights, the respondents to the public consultation consider that they would enhance the protection of privacy and personal data to a high degree (an average of 4.09 on a scale of 1 to 5). SMEs rated the impact similarly at 4.1. The respondents also agreed to a great extent that the requirements would ensure a high level of consumer protection[235]. SMEs also rated the impact high (4.4 out of 5).

6.7. Social impact

Cybersecurity incidents have far-reaching consequences for society. Therefore, enhancing the cybersecurity of products with digital elements would also have positive social impacts such as reduced levels of cybercrime. Moreover, improving the transparency and information of users would have positive impacts for more vulnerable groups of users. Also, the initiative would have a positive effect on the labour market by creating new opportunities for cybersecurity trained specialists.

[235] an average of 4.04 on a scale of 1 to 5.

It is expected that policy options 3 and 4 would ensure a higher level of cybersecurity for products with digital elements and would therefore have a stronger impact in the prevention of cybercrime and on social aspects in general. Since policy option 4 a) and b) would cover also standalone software (only critical for 4 a)), considering the particular relevance of such products (such as apps) with strong social aspects, it would be expected that the positive impact of this policy option in this regard would be the highest.

In addition to the four problem drivers addressed by the Commission's planned intervention, three additional drivers were identified: "lack of bargaining power of users", "lack of qualified security professionals" and "lack of cybersecurity awareness and skills of users". While the initiative would not address those additional drivers directly, policy options 3 and 4 would contribute to a European security culture. Moreover, the additional efforts by manufacturers in raising the level of security of their products could further increase the demand for security professionals and would incentivise more citizens to consider a career in cybersecurity. Finally, as citizens would see the CE marking affixed to a wide range of products having undergone conformity assessment, the intervention would also lead to an increased awareness of the risks associated with products with digital elements, creating incentives for citizens to improve their understanding of cybersecurity issues.

The consultation activities revealed that policy options 3 and 4 are expected to create to the greatest extent additional jobs in the relevant markets and in the whole economy (respectively scoring an average of 5.0 and 6.4 on a scale from 1 to 10 for the former and 5.6 and 6.6 for the latter). Policy options 3 and 4 are also considered to increase the demand for additional or new skills to the largest extent (respectively scoring an average of 6.6. and 7.4 on a scale from 1 to 10).

6.8. Environmental impacts

Strengthening the cybersecurity of products with digital elements could have positive environmental impacts by contributing to wider use of latest generation digital infrastructure and services, which are more sustainable and compliant with the latest environmental standards.

Incidents affecting critical infrastructure and manufacturing could in some instances have a negative impact on the environment, as incidents could result in harmful emissions, waste discharges as well as spills.[236] Even though not many such incidents have occurred so far, cybersecurity experts consider the risk to pipelines or other critical infrastructure to be real.[237] Depending on the policy option, the regulatory intervention could therefore prevent environmental damage by having a positive impact on the resilience of such entities, as it would improve the security of SCADA systems and other hardware and software deployed by critical infrastructure.

Respondents to the open public consultation have rated the actual impact of an environmental damage caused by a cybersecurity incidents affecting products with digital elements as overall moderate. The average rating by all respondents was at 2.31 (on a scale of 1 to 5), with hardware and software manufacturers rating it at 1.82, users at 2.72 and consumer organisations at 5.

While the expected environmental impacts for neither of the policy options would be major, strengthening the cybersecurity of products with digital elements through policy option 4 having the widest scope of application, could have the most positive environmental impacts by contributing to wider use of latest generation of more sustainable digital infrastructure and services. This was confirmed in the targeted consultation, where respondents have indicated that option 4 is be expected to minimise environmental damage to the greatest extent[238], with the other options scoring lower[239].

[236] AXA (2020): "Environmental risks: cyber security and critical industries. An environmental white paper.", p. 1.

[237] Burk and Kallberg (2014): "The Forgotten Threat: The Environmental Consequences of Industrial Cyber Attacks", *American Water Resources Association Annual Water Resources Conference*.

[238] Score of 8.1 on a scale of 1 to 10.

[239] Option 3 at 6.6 and further down to option 0 at 3.1.

7. How do the options compare?

Effectiveness: expected achievement of the objectives

As regards **effectiveness, options 3 and 4 featuring horizontal requirements** are more likely to meet the general and specific objectives set out in *section 4* compared to option 1 and 2, since they entail a regulatory horizontal intervention which would condition the placement on the market of certain or all products with digital elements to the compliance with essential cybersecurity requirements. This would ensure that security would be incorporated in the design and development of these products and that cybersecurity would become a baseline for products with digital elements placed on the internal market, with a high potential to improve the security of these products and also to improve the way users choose such products based on their cybersecurity.

Respondents to the open public consultation agreed that **horizontal requirements** would be the most effective measure, rating them with 4.08 on a scale from 1 to 5. Further voluntary European cybersecurity certification schemes for products with digital elements and services and EU public procurement guidelines taking into account cybersecurity requirements, as foreseen in policy option 1, were rated respectively at 2.99 out of 5, and 3.72 out of 5. Amending existing legislation regulating specific products with a digital dimension (such as the legislation on lifts or gas appliances), as foreseen in policy option 2, rated overall 3.39 out of 5.

In terms of **security requirements**, 90.8% of the stakeholders agreed with the fact that hardware manufacturers and software developers should be responsible for the full life cycle of a product with digital elements. Stakeholders overall rated cybersecurity by design and by default as very effective approaches to contribute to the cybersecurity of products with digital elements, rating them respectively at 4.81 and 4.42 (out of 5, with 5 meaning very effective). Of these two horizontal regulatory options, policy option 4 would be more likely to meet these objectives compared to option 3, since it would also cover in its scope non-embedded software, hence ensuring a higher level of security for a wider scope of products, often dependent on each other.

Furthermore **option 4 b)** would be more effective compared to option 4 a) as it would cover all non-embedded software, while in **option 4 a)** only critical software would be covered. **Option 4 b)** would also have a higher potential to ensure legal certainty and avoid further fragmentation of the internal market with regard to cybersecurity requirements applicable to products with digital elements. Keeping the status quo or relying on ad hoc regulatory interventions as regards cybersecurity or national voluntary schemes, as it would happen under policy options 1 and 2, would by contrast further deepen such fragmentation.

In terms of **scope**, stakeholders agreed with the effectiveness of applying cybersecurity requirements in the following way: hardware products (4.0 out of 5, with 5 indicating that they strongly agreed), embedded software (4.14 out of 5); all standalone software (3.7 out of 5); software products subject to higher cybersecurity risk (4.53 out of 5). While the effectiveness of covering standalone software was rated comparatively lower, this can be explained by a lower support from manufacturers (2.76 out of 5), while users still expressed a strong support (4.03 out of 5). The position of manufacturer is consistent with higher compliance costs linked to the coverage of all software products under policy option 4 b) (see 'efficiency' below).

In terms of conformity assessment, the **sub-option (ii)** establishing two risk categories informing conformity assessment under **policy option 3 and 4a) and b)** would respectively be more effective than options 3i), 4a)i) and 4b)ii) to enhance the security of products with digital elements. The involvement of a third-party body in the testing of higher risk products was broadly supported by stakeholders. 95.10% of the respondents in the public consultation supported the fact that products with digital elements with a higher risk should be subject to a stricter process of demonstrating conformity with these requirements. Only 2.92 (out of 5) agreed that self-declaration of conformity by a hardware manufacturer or software developer gives a sufficient confidence that security requirements are met. 86.15% agreed that involvement of a third party should be required under certain circumstances.

Considering the type of requirements, scope and conformity assessment procedures, policy option 4 b) ii) appears as most effective to reach the specific objectives set in *Section 4*.

Efficiency and economic impacts

Policy options 1 and 2 are likely to bring limited compliance costs, being mostly based on the use of voluntary measures. At the same time, the benefits would equally be limited as they would be mostly related to the reduction of legal uncertainty due to guidance (policy option 1) or the coverage of certain legislative gaps (policy option 2). Amending the RED delegated act to bring in all software would likely increase the benefits under policy option 2 close to policy option 3.

Policy options 3 and 4 would bring respectively significant economic benefits linked to the reduction of costs due to reduced cybersecurity incidents, estimated in the range of respectively EUR 90 to EUR 140 billion under policy option 3), EUR 97 to 158 billion under policy option 4 a) and EUR 180 to 290 billion under policy option 4 b). At the same time, compliance costs would be higher under policy option 3 and 4, compared to policy option 1 and 2. Under policy option 2, an exception is the scenario of broadening the scope of the RED delegated act to non-embedded software that would include higher compliance costs than under policy option 3 and 4 a).

The compliance costs for manufacturers and other economic operators on the supply chain would be triggered both by the design and development of products with digital elements with security as an inherent feature and the conformity assessment processes that go with that. These compliance costs increase with the scope and with mandatory third-party testing. Therefore, they are the highest under policy option 4) b) ii).

The table below presents the overview of all the economic impacts analysed in this report. Concerning the methodology for the comparison of impacts, the report generally operates with the “+/-“ rating system for impacts that were qualitatively assessed. To the extent possible, were quantitative data was available, the net impact and cost-benefit ratio has been estimated.

The table evidences the **net positive impact** increasing with a broadened scope between policy option 3 and 4. The net positive impact is the highest for policy option 4 and its respective sub-options. While no granular quantitative data is available, it is reasonable to assume that the net positive impact would be the highest for policy option 4b) ii).

It is not possible to define a detailed **cost-benefit ratio comparison** of sub-options. The cost-benefit ratio which is higher for policy option 3 compared to 4 can be explained by the absence of granular quantitative data for benefits at the level of sub-options. While the benefits "only" double between policy option 3 and 4, the compliance costs increase more significantly as software products have lower BaU costs, e.g. for testing. Furthermore, the software market is slightly bigger compared to the hardware market[240]. At the same time, benefits in terms of reduction of cyber incidents, competitiveness and prevention of internal market fragmentation increase with a broadened scope, and are expected to be the highest under policy option 4) b) ii).

Under options 3 to 4 and their respective sub-options, the effects of additional compliance costs will have a larger relative cost impact on **SMEs** than on large companies. Such compliance costs would be the highest under policy option 4 b) ii). Even though the relative cost increases are higher for SMEs, the impact on SMEs overall costs is still considered moderate when measured against the benefits that would result from a reduced number of cybersecurity incidents that would be most significant under policy option 4 b) ii). SMEs rated the costs of voluntary measures in average at 3.1 out of 5 (with 5 indicating very costly), compared to 3.6 for policy option 2, and around 3.5 out of 5 for horizontal requirements.

[240] Hardware products represent 48% of the relevant market, compared to 52% for the software market.

For **Member States and public authorities**, the direct costs would increase with a broader scope of products to be monitored, hence the direct costs would be the highest under **policy option 4 b)**. For the same scope, enforcement costs are expected to be higher without third party-assessment, under policy option 3 i) and 4a)i) and 4b)i) compared to 3 ii) and 4 a)ii) and 4b)ii). Public authorities will benefit under policy option 3 and 4 as users of products with digital elements from an enhanced security of products and reduced costs due to less cybersecurity incidents. Market surveillance authorities could also benefit in terms of efficiency from alignment of the provisions for market surveillance for harmonised and non-harmonised products with digital elements. Such benefits are expected to be the highest under policy option 4 b) ii).

Consumers will benefit from the reduction of unsecure products with digital elements on the market. The trend of the impact of the different options on the reduction of costs due to cybersecurity incidents can be reasonably assumed to be similar as for businesses. Hence, they can expected to be the highest under policy option 4 b) ii). Consumers might face higher end-user prices on products with digital elements, which can be expected to be the highest under option 4 b) ii). However, these are not expected to be significant both in terms of quantitative and qualitative value to the consumers and will decrease over time (see *section 6.3.4*).

	Key Costs/benefits	**Policy options**							
		PO 1	**PO 2**	**PO 3**		**PO 4**			
				3 (i)	3 (ii)	4a)		4b)	
						4a) i)	4a)i)	4b)i)	4b)ii)
	Businesses								
Costs	Compliance costs (for average product development cost of 140 000 EUR)	*Neutral/+*[241]	+/++[242]	**EUR 11.2 bn**	**EUR 11.3 bn**	**13 bn EUR**	**13.1 bn EUR**	**EUR 28.8 bn**	**EUR 29 bn**
	Compliance costs for SMEs [243]	+	++	++	++	++	++	+++	+++
	Standardisation costs	*Neutral*	++	+	+	++	++	+++	+++
	End-user prices (indirect)	*Neutral/+*	*Neutral/+*	+	+	++	++	+++	+++
Benefits	Cost savings due to reduced cyber incidents	*Neutral*	+	**EUR 90 billion to EUR 140 bn annually**		**EUR 97 bn to EUR 158 bn**		**EUR 180 to 290 bn annually**	

[241] Due to the voluntary nature, compliance costs to be compensated by benefits. However, compliance costs can occur through an indirect market pressure in case of uptake of voluntary measures by the demand side (public procurement guidelines, EU certification).

[242] Additional compliance costs depending on sectoral legislation, possibly high in the case of amendment of RED to include standalone software.

[243] Based on feedback received in open public consultation: SMEs rated the costs of voluntary measures in average at 3.1 out of 5 (with 5 indicating very costly), compared to 3.6 for policy option 2, and around 3.5 out of 5 for horizontal requirements respectivel on software and hardware.

	Prevent internal market fragmentation[244]	*Neutral/ -*	*Neutral / -*	+	+	++	++	+++	+++
	Increased competitiveness & uptake of products with digital elements	*Neutral*	*Neutral*	+	+	++	++	+++	+++
	Net value*				**EUR 77.8 - 127.8 bn**		**EUR 93 bn - 144.9 bn EUR**		**EUR 151-261 bn**
	Cost benefit ratio*				**7.4 - 11.5**		**7.4 - 12.1**		**6.2 - 10**
	Public authorities								
Benefits	Reduced cyber incidents	*Neutral*	+	++	++	++/+++	++/+++	+++	+++
Costs	MS authorities - enforcement costs (average for products on the market)	*Neutral/+*[245]	*++*[246]	**EUR 3.1 bn**	**EUR 3.1 bn**	**EUR 3.6 bn**	**EUR 3.6 bn**	**EUR 7.7 bn**	**EUR 7.7 bn**
	ENISA - collecting and disseminating information on exploited vulnerabilites	*N.A.*	*N.A.*	**2.5 FTEs**	**2.5 FTEs**	**3.5 FTEs**	**3.5 FTEs**	**4.5 FTEs**	**4.5 FTEs**

[244] Based on responses from open public consultation

[245] Additional costs for market surveillance authorities if a new EU certification scheme is implemented. For voluntary measures, like guidelines, no costs expected.

[246] Additional enforcement and adjustement costs for MSAs due to addition of cybersecurity requirements, and possibly standalone software

	(redistribution of ressources)								
	Consumers								
Benefits	Reduced cyber incidents	*Neutral*	+	++	++	++/+++	++/+++	+++	+++
	Enhanced consumer choice & transparency[247]	+	+	++	++	++	++	+++	+++
Costs	End-user prices (indirect)	*Neutral/+*	*Neutral/+*	+	+	++	++	+++	+++

***** *based on available quantitative data*

Table 9: Comparison of policy options according to the economic impact and efficiency

[247] based on feedback from the open public consultation

Social impacts, impacts on fundamental rights and environmental impacts

As regards the **social impact,** as well as the impact of **fundamental rights**, and notably data protection and protection of privacy, it is expected that policy options 3 and 4 would have a more positive impact, as attacks affecting insecure products with digital elements have serious consequences in the personal sphere and for society as a whole. Therefore, these two policy options, which would ensure a higher level of cybersecurity for these products, would be more impactful on fundamental rights and social aspects. Since policy option 4 a) and b) would cover also standalone software, considering the importance of such products (such as apps) for social aspects and personal data, it would be expected that the positive impact would be the highest for policy option b). Furthermore, third-party assessment would increase the assurance level of the security of higher risk hardware and software products, hence the social impact and impact on fundamental rights would be the highest for policy option 4 b) ii).

No major **environmental** impact is expected for any of the policy options considered. However, strengthening the cybersecurity of products with digital elements notably through policy option 4 which would have the widest scope of application could have positive environmental impacts by contributing to wider use of latest generation digital infrastructure and services, which are more sustainable.

Coherence

As regards the coherence with the **EU strategic policy priorities in the area of cybersecurity**, policy options 3 and 4 would deliver the most on the establishment of common European cybersecurity standards for connected products as forseen under the EU's Cybersecurity Strategy for the Digital Decade[248]. Policy option 4 b), presenting the widest scope and covering all products with digital elements, would be the most aligned with the announced objective.

Regarding other **horizontal EU legislation in the area of cybersecurity**, both **policy 3 and 4** would present strong synergies with the supply chain security requirements included in the **NIS2 Directive**, now close to completing adoption. Entities under NIS2 will have to consider the vulnerabilities specific to each direct supplies (such as of software for example) and the overall quality of products and cybersecurity practices of their suppliers, including development procedures. Horizontal requirements for all products with digital elements, including third-party assessment for higher risk products, as foreseen under **policy option 4 b) ii)**, would strengthen this provision most and close the circle of supply chain security guarantees.

Regarding the **EU Cybersecurity Act**, policy option 1 would be the most coherent as it foresees to continue developing such schemes. However, both under policy option 3 and 4, a certificate or statement of conformity issued under an European cybersecurity certification scheme may be used to demonstrate the presumption of conformity with requirements of that legal act.

As regards the coherence **with other relevant product legislation**, both policy options 3 and 4 and respective sub-options, would include specific cybersecurity requirements of the likes that are not currently covered by the NLF legislation. Furthermore, the act setting out the horizontal cybersecurity requirements would set out a rule of the type of *lex specialis,* specifying that where, for a certain category of products with digital elements, the cybersecurity risks addressed by the essential requirements are covered by other more specific requirements of other Union harmonization legislation, these horizontal

[248] JOIN(2020) 18 final.

requirements shall not apply to those products to the extent that that specific Union legislation covers such risks.

As regards the RED Delegated Regulation for inter-connected radio equipment, it would be implemented until the horizontal requirements start applying. As the horizontal requirements would be more specific, the RED Delegated act requirements would become obsolete. Alternatively, compliance with the horizontal cybersecurity requirements could be presumed to provide compliance with the cybersecurity requirements of RED delegated act. Moreover, when preparing the standardisation request for the horizontal cybersecurity requirements, it will be ensured that the standardisation work done for the RED Delegated Regulation is preserved and complemented only where needed.

When it comes to the coverage of the whole life cycle and duty of care, policy options 3 i) and ii) and 4 a) and b) would be compatible with the future EU framework on liability for defective products, to be reviewed, which is expected to introduce liability for situations when damages are triggered by vulnerabilities. The liability of an economic operator may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person [including, for example, rejecting a software security update] or any person for whom the injured person is responsible.

Proportionality

As regards the **proportionality of the intervention**, policy options 3, 4 a) and b) do not go beyond what is necessary to meet the specific objectives satisfactorily. Any additional compliance costs would be outweighed by the benefits brought by a higher level of security of products with digital elements and ultimately an increase of trust of users in these products. For these reasons, but also for the need to ensure legal certainty and avoid any further fragmentation of product-related requirements on cybersecurity on the internal market, the open public consultation and the targeted consultation have shown a wide overall **support of various stakeholders**, both industry and national authorities for a horizontal intervention setting out cybersecurity requirements for products with digital elements.

Stakeholder support

In the public consultation, respondents were asked to rate the effectiveness of various types of policy interventions ranging from further voluntary certification schemes and amending existing legislation regulating specific products to mandatory horizontal cybersecurity requirements for hardware and software. Respondents agreed that **horizontal requirements for hardware and software would be the most effective measure**, and rated it respectively 4.08 and 4.09 on a scale from 1 to 5. This includes consumer organisations (5.00), respondents identifying themselves as users (4.22), notified bodies (4.17), MSAs (5.00) and manufacturers of products with digital elements (3.85), as well as SME users and manufacturers (4.05). The other types of interventions were rated as follows:

- Further voluntary European cybersecurity certification schemes for products with digital elements and services: overall (2.99), national market surveillance bodies (2.0), consumer associations (1.3), public administrations as users (2.9), SMEs as users (3.2), hardware manufacturers (2.5), software manufacturers (3.4), SMEs in their role as manufacturers (2.7).
- EU public procurement guidelines taking into account cybersecurity requirements: overall (3.72), national market surveillance bodies (2.5), consumer associations (2.3), public administrations as users (4.1), SMEs as users (4.2), hardware

manufacturers (3.3), software manufacturers (4.1), SMEs in their role as manufacturers (3.7).

- Amending existing legislation regulating specific products with a digital dimension (such as the legislation on lifts or gas appliances): overall (3.39), national market surveillance bodies (3.5), consumer associations (3.0), public administrations as users (4.5), SMEs as users (3.5), hardware manufacturers (2.2), software manufacturers (3.3), SMEs in their role as manufacturers (2.1).

There are several reasons why policy option 4 is broadly supported by the manufacturers of products with digital elements despite the relatively high cost compared with other types of intervention. First of all, the security of products with digital elements also depends on the security of components integrated into those products. Manufacturers therefore have to rely on their upstream supply chain manufacturers taking security seriously. A horizontal intervention would ensure that manufacturers could integrate components developed to meet certain security requirements. Secondly, a horizontal intervention would provide manufacturers with a high degree of legal certainty, as it would do away with the current piecemeal approach of Union NLF product legislation when it comes to cybersecurity. Finally, under a horizontal intervention, higher costs related to cybersecurity would no longer translate into a competitive disadvantage for manufacturers, as their direct competitors would be required to develop products living up to the same high standards. As stressed under 'efficiency', there is nevertheless a concern by manufacturer regarding the compliance costs related to the inclusion of all non-embedded software into the scope of a possible horizontal initiative (as foreseen under option 4b). On the contrary, such an approach is strongly supported by users.

Overview and overall assessment of all policy options

The table below presents a simplified overview of negative and positive impacts by type of impact.

Impacts	Option 0 *Status quo*	Option 1 *Soft law*	Option 2 *Ad-hoc interv.*	Option 3 *Mixed approach*		Option 4 *Horiz. Interv.*	
				3 i)	3 ii)	4 a)	4 b)
						4 a) i)	4 b) ii)
Effectiveness	⬜⬜⬜	🟥⬜⬜	🟥🟩⬜	🟩⬜⬜	🟩⬜⬜	🟩🟩⬜	🟩🟩🟩
Economic/Efficiency	⬜⬜⬜	🟩⬜⬜	🟩⬜⬜	🟩🟥⬜	🟩🟥⬜	🟩🟩🟥	🟩🟩🟥
Environmental	⬜⬜⬜	🟩⬜⬜	🟩⬜⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩⬜
Social	⬜⬜⬜	🟩⬜⬜	🟩⬜⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩🟩	🟩🟩🟩
Fundamental rights	⬜⬜⬜	🟩⬜⬜	🟩⬜⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩🟩	🟩🟩🟩
Coherence	⬜⬜⬜	🟩⬜⬜	🟩⬜⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩🟩	🟩🟩🟩
Stakeholder support	⬜⬜⬜	🟩🟥⬜	🟩🟥⬜⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩🟩	🟩🟩🟩
Proportionality	⬜⬜⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩⬜	🟩🟩⬜
Total	⬜⬜⬜⬜⬜⬜⬜⬜⬜ ⬜⬜⬜ ⬜⬜⬜⬜⬜⬜⬜⬜⬜ ⬜⬜⬜	🟩🟩🟩🟩🟩🟩🟩🟩🟥 🟥⬜⬜ ⬜⬜⬜⬜⬜⬜⬜⬜⬜ ⬜⬜⬜	🟩🟩🟩🟩🟩🟩🟩🟩🟩 🟥🟥⬜ ⬜⬜⬜⬜⬜⬜⬜⬜⬜ ⬜⬜⬜	🟩🟩🟩🟩🟩🟩🟩🟩🟩 🟩🟩🟩 🟩🟩🟥⬜⬜⬜⬜⬜⬜ ⬜⬜⬜	🟩🟩🟩🟩🟩🟩🟩🟩🟩 🟩🟩🟩 🟩🟩🟥⬜⬜⬜⬜⬜⬜ ⬜⬜⬜	🟩🟩🟩🟩🟩🟩🟩🟩🟩 🟩🟩🟩 🟩🟩🟩🟩🟩🟩🟩🟩🟥 ⬜⬜⬜	🟩🟩🟩🟩🟩🟩🟩🟩🟩 🟩🟩🟩 🟩🟩🟩🟩🟩🟩🟩🟩🟩 🟥⬜⬜

The symbols 🟩 and 🟥 indicate respectively positive and negative impacts as compared to the status quo. For each symbol a maximum scale of 1 to 3 (maximum positive or negative assessment) is used.

Table 10: Overall impact of the various policy options

While **Option 1** is causing no major additional costs for businesses and MSAs, it is unlikely to be adequate to address the problems identified. While legal uncertainty will be slightly reduced due to Commission guidance, it will not have the effect to significantly changing security market practices. Option 1 is also expected to deepen market fragmentation in the absence of horizontal cybersecurity requirements.

Option 2 is causing limited compliance costs except under the scenario where the RED delegated act would be extended to include all software, where compliance costs would be high (for economic operators and MSAs). Option 2 would only partially adequately address the identified problems, as gaps will remain regarding the coverage of hardware (e.g. wired hardware). Furthermore, option 2 could also have the effect of deepening market fragmentation by taking a product-specific approach instead of introducing horizontal requirements.

Option 3 is linked to somewhat higher additional compliance costs, however lower than Option 2 (under the scenario of amending RED delegated act). Horizontal requirements for hardware and software received strong stakeholder support. Both under 3i) and 3ii) horizontal requirements would avoid market fragmentation for hardware products and embedded software. While compliance costs would slightly increase under option 3ii), mandatory third-party assessment for higher risk products would be even more effective to enhance cybersecurity, and ease market surveillance. However, under option 3, a significant gap would remain for enhancing cybersecurity of and preventing market fragmentation for non-embedded software products.

Option 4 would lead to higher costs for businesses and market surveillance authorities, while such costs would be lower under option 4 a) if only critical software is covered, compared to option 4 b). Option 4a) including third-party assessment received strong stakeholder support. Most stakeholders disagreed that self-assessment could be sufficient. However, option 4 a)ii) would again leave a gap for a large part of the software market (estimated at 90%).

Option 4 b) including third-party assessment would bring the most significant compliance costs. It was nevertheless strongly supported by stakeholders. The compliance costs would be proportionate to the significant cost savings that can be drawn from reduced cybersecurity incidents and from having to comply with multiple product-specific cybersecurity requirements. Under option 4 b)ii) mandatory third-party assessment for higher risk products would be even more effective to enhance trust of users, and ease market surveillance, while higher compliance costs would be limited to a narrow category of products presenting a higher risk.

8. PREFERRED OPTION

8.1. Rationale and benefits of the preferred option

Policy option 4 sub-option b) ii) emerges as the preferred option based on the assessment of effectiveness against the specific objectives and efficiency of costs versus benefits, and coherence with the existing EU and policy framework. The option would deliver the best results, while compensating higher compliance costs with significant cost savings. It would have the highest compliance costs, both for businesses and MSAs and slightly higher prices for end-users. However, it would also bring the highest benefits in terms of costs savings due to the reduction of cybersecurity incidents and harmonised cybersecurity requirements. Furthermore, additional compliance costs for conformity assessment would only apply to a limited category of products justified on the basis of their higher risk.

Option 4 b) would ensure the setting out of specific horizontal cybersecurity requirements for all products with digital elements being placed, made available in the internal market, and would be the only option covering the entire digital supply chain. Standalone software, equally exposed to vulnerabilities, would also be covered by such regulatory intervention, thus ensuring a coherent approach towards all products with digital elements, with a clear share of responsibilities of various economic operators. This would ensure a design and development of products with digital elements that would have cybersecurity as an ingrained feature, while at the same time guaranteeing a proportionate approach that would avoid unnecessary burden on manufacturers and the other economic operators on the value chain. The security requirements set out would be objective-oriented and not product- or sector-specific, while at the same time ensuring sufficient granularity to generate a tangible impact on the level of cybersecurity of products with digital elements.

As regards the way in which manufacturers would be able to demonstrate conformity with the security requirements, sub-option (ii) emerges as the preferred choice: two risk categories informing self-assessment (by default), third-party conformity assessment (for critical products). Sub-option (ii) is proportionate, as the vast majority of products with digital elements would be subject to self-assessment, which is generally associated with the lowest administrative burden and compliance costs for manufacturers. At the same time, it would also be effective in ensuring an adequate level of assurance for a small number of products carrying a higher risk, by subjecting these products to mandatory third-party conformity assessment.

This policy option also brings added value by covering duty of care and whole life cycle aspects after the placement of the products with digital elements on the market, to ensure, among others, appropriate information on security support and provision of security updates.

This policy option would also come to most effectively complement the recent review of the NIS framework, by ensuring the prerequisites for a strengthened supply chain security.

8.2. Application of the ‘one in, one out’ approach

"INs": administrative costs related to third-party assessment (certification), documentation and reporting

The preferred option is likely to lead to an increase of compliance costs for businesses. The total market affected is detailed in section 5.1, and would represent a total turnover of up to EUR 1 485 billion and 615 272 companies/products (see also *Annex 3*). First, hardware and software manufacturers will be impacted by adjustment costs as a result of the new and additional cybersecurity requirements and internal testing costs. And secondly, conformity assessment procedures involving a third-party when placing products on the market and documentation requirements will lead to additional administrative costs. These adjustment and administrative costs and the methodology behind them are explained in detail in section 6, including the limitations behind these quantitative estimates.

In total, it is estimated that this initiative would lead to **additional administrative costs of approximately EUR 8.9 billion** for the whole of the EU ('IN'), taking into account BaU costs. **The one-off administrative costs would amount to EUR 7.6 billion, with**

recurrent costs of EUR 1.3 billion. These costs have to be put into perspective with the administrative savings linked to this initiative ('OUT') detailed below.

The administrative costs under the preferred option are estimated under *section 6*, and summarised in *table 7*. They include the costs related to certification that would apply to 10% of the market (estimated share of critical products with digital elements, estimated at EUR 1.1 bn, or 25 000 EUR by company/product with BaU costs at 40% for hardware manufacturers and 25% for software manufacturers, see *Annex 4*) and costs related to conformity other than certification (EUR 7.8 bn, or 12 600 EUR by company/product). The impacted market is represented by the indicators SD and ICT-EXT-ADJ. Furthermore, the assumption is taken of one product by company and an average product development cost of 140 000 EUR.

In order to distinguish between **one-off and recurrent costs**, regarding the third-party assessment costs, at a level of a company, for each new product that has to be tested the one-off costs will be higher than recurrent costs, therefore it is assumed that 70% of the costs represent one-off costs (e.g. auditing and reviewing of documentation by external party and fees to notified body) and that 30% represent recurrent costs related to the maintenance of the certification (e.g. regular audit for the maintenance of the certification). However, this differentiation of one-off and recurrent costs could not be corroborated by secondary or primary data.

Regarding other types of administrative costs, including documentation and reporting, no granular data is available. For documentation and information obligations, it is estimated that the one-off costs would be slightly higher (linked to the creation of the documentation), while recurrent costs would still exist due to the obligation for the manufacturer to keep its documentation up to date and to provide information to the users throughout the lifecycle. A significant part of the other types of administrative costs could be linked to reporting obligations. The costs of reporting obligations would be both one-off (e.g. putting in place a reporting system) and recurrent. Based on the primary data gathered[249], it is assumed that the documentation and reporting obligations would respectively represent 60% and 40% of the total costs. Furthermore, both for documentation and reporting obligations, one-off costs would be higher than recurrent costs, and can be estimated respectively around 12.5%[250] based on the same primary data.

In detail, the administrative costs related to documentation and reporting can be described as follows:

- Requirements related to the declaration of conformity and marking of the digital products
    - Where compliance of the product with the applicable requirements has been demonstrated by that procedure, draw up an EU declaration of conformity and affix the CE marking.
    - Keep the EU declaration of conformity up-to-date.
    - Ensure that each digital product is accompanied by a copy of the EU declaration of conformity.
    - Keep the EU declaration of conformity for 10 years after the product has been placed on the market.

[249] Targeted survey on impacts launched on 16 May 2022 organised by the study supporting this impact assessment. As mentioned in section 6, this data could not be verified and has been used in the absence of secondary data.

[250] Targeted survey on impacts launched on 16 May 2022: in the responses, stakeholders indicated ranges between 1% and 25%.

  - Keep a register of complaints, non-conforming products and product recall, and keep distributors informed of any such monitoring.
  - Ensure that products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.
  - Indicate the manufacturers' name, registered trade name or registered trademark, and the address at which they can be contacted, on the product or, where that is not possible, on its packaging or in a document accompanying the product.
- Requirements related to reporting of the digital products
  - Report to ENISA exploited vulnerabilities and incidents having an impact on the security of the product with digital elements.
  - Inform the user about any incident having an impact on the security of the product with digital elements.
  - Immediately inform the relevant national competent authority should the product present cybersecurity risks that pose threats to the general public or the life and health of persons.
  - Upon identifying a vulnerability in an open-source component and where the manufacturer or developer has integrated the component into its product, report the vulnerability to the maintainer of the component.
  - Further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product, in a language, which can be easily understood by that authority. Cooperate with that authority, at its request, on any action taken to eliminate cybersecurity risks posed by the product, which they have placed on the market.
- Requirements related to technical documentation of the digital products
  - Draw up the necessary technical documentation before the product is placed on the market in a language that is accepted by the notified body.
  - Keep the technical documentation up-to-date.
  - Keep the technical documentation for 10 years after the product has been placed on the market.
  - Make the technical documentation available to authorities upon request.

The table below summarises the administrative costs related to certification, documentation and reporting for one company/product, and at aggregated level. The costs are based on the products currently available on the market (using the SD and ICT-EXT-ADJ indicators), as it is not possible to estimate how many products will arrive on the market every year. In practice, the new obligations under the preferred option would only apply after a transition period to new products placed on the market (grandfathering clause). The recurent costs are assumed to be annual. These estimations were made based on limited quantitative data available. Therefore, the first evaluation of this initiative (see *Section* 9) should explore a more granular assessment of the administrative costs on businesses.

Per company	One-off costs	Recurrent costs (annual)	Total
Administrative costs linked to testing			

Certification for critical products (third-party conformity assessment)	• By company/product: EUR 17 500 • Aggregated costs: EUR 0.8 bn (70% of the costs are audit cost by the notified body to obtain the certification)	• By company/product: EUR 7 500 • Aggregated costs: EUR 0.3 bn (30% are related to monitoring the certification,)	• Average by company/product 25 000 EUR (with BaU costs of 40% for hardware manufacturers and 25% for software developers) • Aggregated: **EUR 1.1 bn**
Other administrative costs : documentation and reporting			
Documentation, such as creation and updating of technical documentation, EU declaration of conformity; affixing the CE marking; Creation of and updating the risk assessment; Information and instructions for the user, including when providing software updates.	• By company/product: 6615 • Aggregated costs: EUR 4.1 bn	• By company/product: 945 EUR • Aggregated costs: EUR 0.6 bn	• **by company/product: 9% of product development costs** (in average additional EUR 12 600, of which EUR 7560 documentation and 5040 reporting costs, for average product development costs of 140 000 EUR) • Aggregated: **EUR 7.8 bn** (of which EUR 4.7 bn for documentation and EUR 3.1 bn for reporting)
Reporting to market surveillance authorities Reporting of exploited vulnerabilities and cybersecurity incidents to ENISA	• By company/product: EUR 4410 • Aggregated costs: EUR 2.7 bn	• By company/product: EUR 630 • Aggregated costs: EUR 0.4 bn	
TOTAL	• By company/product (in average): EUR 25 060 (for average development costs of 140 000 EUR, ca. 17% additional product development costs) • Aggregated average: **EUR 7.6 bn**	• By company (in average): EUR 12 540 for average development costs of 140 000 EUR, ca. 9% additional product development costs) • Aggregated average: **EUR 1.3 bn**	• by company/product covered by the initiative: EUR 37 600, ca. 26% additional product development costs, for an average of 140 000 product development costs. • Aggregated: **8.9 bn EUR**

Table 11: Overview of one-off and recurrent administrative costs

"OUTs": administrative savings due to reduced compliance costs with the upcoming NIS2 Directive

The administrative costs should be offset with **removed administrative costs** linked to the initiative. In total, these administrative cost savings are estimated to represent approximately **EUR 6.95 billion**. Administrative costs savings are related to two main sources. First, the initiative will facilitate compliance with administrative costs related to supply chain managamenet under the upcoming NIS2 Directive. Second, the initiative will prevent fragmented rules at national and EU level related to the cybersecurity of products with digital elements. Only the first source of potential administrative savings could be quantified.

Under the upcoming NIS2 Directive[251], entities must take cybersecurity risk management measures, including measures to secure their supply chains. The approximately 110 000 entities in the scope of NIS2 would therefore experience significant cost savings brought about by the preferred policy option, which would enhance the security of the products with digital elements used in the whole supply chain[252]. Supply chain requirements under NIS2 would for instance include managing the contractual relationships with suppliers and auditing suppliers to verify that purchased products comply with the cybersecurity requirements. In the context of the Impact Assessment of the NIS2 Directive, the costs related to **"Security elements concerning supplier relationships and supplier-specific risk assessment**" where estimated as one-off costs of hiring in average **1 FTE by company** , and a potential increase of **2-4% in recurrent purchase ICT security costs**. One FTE position can be estimated at a cost of EUR 66 560[253], which would represent EUR 7.3 billion one-off costs for the 110 000 entities covered by NIS2. According to the Commission's impact assessment for the revision of the NIS Directive, the average ICT security spending of companies in 2020 is of approximately 9.14 % of their ICT spending.[254] According to an ENISA survey[255], the median spending of an entity covered by NIS for IT security spending was EUR 2 million per entity in 2020, which leads to an aggregated value of EUR 220 billion, of which 2-4% (taking an average of 3%) would amount to EUR 6.6 billion recurrent costs.

Taking into account that the initiative will not apply directly to IT services[256], it is assumed that the initiative would lead to **50% of compliance cost reduction** with the requirement related to supply chain security for essential and important entities. Hence, the cost savings would respectively represent in total **EUR 6.95 billion**, **with EUR 3.65 billion from one-off costs and EUR 3.3 billion recurrent costs**.

Cost savings	One-off cost savings	Recurrent cost savings

[251] The entry into force of the NIS2 Directive is planned 21 months after its publication in the Official Journal. A political agreement on the NIS2 Directive was reached in May 2022.

[252] See Article 21.2 (d) the compromise text of the NIS2 Directive from 17 June 2022: "(d) supply chain security including security-related aspects concerning the relationships between each entity and its direct suppliers or service providers".

[253] With following assumptions: 40 hours per week x 52 weeks per year = 2,080 hours ; hourly wage of 32 Euros (See *Impact Assessment* for AI Act)

[254] SWD(2020) 345 final, IA accompanying the NIS2 proposal, p. 71.

[255] https://www.enisa.europa.eu/publications/nis-investments-2021

[256] According to the study "The Economic and Social Impact of Software & Services on Competitiveness and Innovation" (SMART 2015/0015) prepared for the European Commission, cloud computing represented 18.3% of the software market in 2020, and infrastructure and application-related IT services respectively 21.2% and 29.3%.

Costs savings on compliance with NIS2 obligations (supply chain security requirement for essential and important entities)	- By company: 0.5 FTE (in average: EUR 33 280) for NIS entities - Aggregated average: EUR 3.65 bn	- By company: 1-2% additional ICT security spending, for NIS entities (around 30 000 EUR by company, taking an average of 1.5%) - Aggregated average: EUR 3.3 bn
Administrative costs	- Aggregated average: EUR 7.6 bn	- Aggregated average: EUR 1.3 bn
Total Administrative burden *(administrative costs minus cost savings)*	- Aggregated: EUR 3.95 bn	- Aggregated: - EUR 2 bn

Table 12: Overview of cost savings and total administrative burden

Moreover, cost savings would stem from hvaing one horizontal framework. Tnstead of potentially conflicting rules at national level or a piecemeal approach at EU level, the preferred option is likely to offset compliance costs by introducing one set of streamlined requirements for the same type of product with digital elements at EU level, which would reduce regulatory costs for the manufacturers. Indeed, most stakeholders favour a harmonised and coordinated approach at the EU level as revealed in the open public consultation, targeted survey, workshops and interviews. However, the costs related to streamlining security requirements could not be estimated.

Taking into account on the one side, the administrative costs related to the initiative under the preferred policy option and on the other side, the administrative savings, the **total administrative burden of the preferred option for businesses operating in Europe**[257] would be of approximately **EUR 1.95 billion**, for an overall market value covered by the initiative of up to EUR 1317 billion in production value and EUR 1485 billion in turnover (based on 2019).

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

By [36 months] after the date of application of the initiative and every four years thereafter, the Commission shall submit a report on the evaluation and review of the initiative to the European Parliament and to the Council. The report shall be made public. The application of the regulation should in principle be set for approximately 24 months following its entry into force, to allow sufficient time to the economic operators to adapt and prepare adequate implementation.

As regards the monitoring of the impact of the regulation, certain indicators would be considered for this purpose, to be assessed by the Commission, where appropriate with the support of ENISA. Depending on the operational objective to be reached, some of the monitoring indicators based on which the success of the horizontal cybersecurity requirements would be assessed are as follows:

A. For assessing the **level of cybersecurity of products with digital elements**:

[257] This report cannot distinguish between EU and non-EU businesses.

- ✓ Statistics and qualitative analysis on incidents affecting products with digital elements and the way these were handled. These could be gathered and assessed by the Commission and be based on the information reported to ENISA.
- ✓ Records of known vulnerabilities and analyses of how these were handled. Such analysis could be conducted by ENISA, based on the European vulnerability database set up based on NIS2 and information reported to ENISA under this initiative.
- ✓ Surveys amongst manufacturers of hardware and software to monitor progress.

B. For assessing the **level of information on security features, security support, end-of-life and duty of care**: results of surveys to be conducted by the Commission, with support from ENISA for both consumers and businesses.

C. For assessing the implementation, the Commission would aim to ensure that the **conformity assessments are effectively performed**. To this end, the coordination of notified bodies will be promoted. Furthermore a standardization request could be issued and its implementation followed. The Commission will also verify the capacity of the notified bodies.

D. As regards the **application**, by means of the reports of Member States, the Commission will verify that national initiatives do not concern aspects covered by the regulation.

The following table lists provisional and non-exhaustive indicators, indicating how meeting the set general and specific objectives can be measured.

Specific objective	***Indicator***	***Baseline***	***Frequency***	***Target***	***Source***
Ensure that manufacturers improve the security of their products with digital elements since the design and development phase and throughout the whole life cycle of those products	*Number of serious incidents in the Union resulting from vulnerabilities in products with digital elements*	*2024*	*Annual*	*Reduction of incidents by roughly 20 to 33 % (difficult to measure as other developments may influence the outcome)*	*Aggregate incident reporting mechanism under the NIS2*
	Share of hardware and software manufacturers that follow a systematic secure development life cycle	*2024*	*Biennial*	*100 %*	*Surveys amongst hardware and software manufacturers*
	Qualitative analysis of the security of products with digital elements	*2024*	*Biennial*	*n/a*	*ENISA, surveys amongst security experts*

	Maturity of secure development practices in manufacturers: *—quantitative and qualitative assessment of vulnerability databases;* *—frequency of security patches made available by manufacturers;* *—average number of days between vulnerability discovery and the provision of security patches*	*2024*	*Biennial*	*—Reduction of vulnerabilities by 20 to 33 % (difficult to measure as other developments may influence the outcome)* *—Higher frequency of patches* *—Shorter average number of days between vulnerability discovery and the provision of security patches*	*ENISA, market surveillance, surveys amongst security experts, European vulnerabilities database set up on the basis of NIS2, cybersecurity studies*
Ensure a coherent cybersecurity framework	*Absence of targeted product-specific national cybersecurity legislation*	*2024*	*Biennial*	*Absence of targeted product-specific national cybersecurity legislation*	*Surveys, studies, TRIS notification procedure under Directive 2015/1535*
Enhance the transparency as regards the security properties of products with digital elements	*Share of products with digital elements that are shipped with information on security properties*	*2024*	*Biennial*	*100 % of products with digital elements shipped with information on security properties*	*ENISA, market surveillance bodies, studies*
Enable organisations and consumers to use products with digital elements securely	*Share of products with digital elements that are shipped with user instructions on secure use*	*2024*	*Biennial*	*100 % of products with digital elements shipped with user instructions on secure use*	*ENISA, market surveillance bodies, studies*

Table 13: Indicators for monitoring and evaluation

GLOSSARY OF ABBREVIATIONS

Acronym	Meaning
AI	Artificial Intelligence
B2B	Business to Business
B2C	Business to Customer
BaU	Business as Usual
CAGR	Compound Annual Growth Rate
CLA	Cybersecurity Labelling Scheme
CN	Combined Nomenclature
CPU	Central Processing Unit
CRA	Cyber Resilience Act
CSD	Consumer Sales Directive
CSIRTs	Cyber Security Response Teams
DDoS	Distributed Denial of Service
DoC	Declaration of Conformity
DoP	Declaration of Performance
eIDAS (Regulation)	Regulation on electronic identification and trust services for electronic transactions in the internal market
ENISA	European Union Agency for Cybersecurity
EO	Executive Order (US)
FTE	Full Time Equivalent
GDPR	General Data Protection Regulation
GPSD	General Product Safety Directive
GPSR	General Product Safety Regulation (proposal)
IA	Impact Assessment
IaaS	Infrastructure as a service (cloud service model)
ICS	Industrial Control System
ICT-SC	ICT – standard classification
IoT	Internet of Things
METI	Ministry of Economy, Trade and Industry of Japan
MDR	Medical Devices Regulation
MID	Measuring Instrument Directive
MR proposal	Machinery Regulation Proposal
MSA	Market Surveillance Authority

MSD	Market Surveillance Services Directive
MSR	Market Surveillance Regulation
NIS (Directive)	Directive concerning measures for a high common level of security of network and information systems across the Union
NIST	National Institute of Standards and Technology – US Department of Commerce
NLF	New Legislative Framework
NTIA	National Telecommunications and Information Administration (US)
OSS	Open Source Software
OT	Operational Technology
OWASP	Open Web Application Security Project
PaaS	Platform as a service (cloud service model)
PED	Pressure Equipment Directive
RED	Radio Equipment Directive
RRD	Recreational Craft and Personal Watercraft Directive
SaaS	Software as a Service (cloud service model)
SBOM	Software Bill of Materials
SDLC	Secure Development Life Cycle
SMEs	Small and Medium-sized Enterprises
SOCs	Security Operation Centres
TFEU	Treaty on the Functioning of the European Union
TSD	Toy Safety Directive

GLOSSARY OF TERMS AND DEFINITIONS

Term	Meaning or definition
Ancillary service	A digital service the absence of which would prevent the product [tangible and intangible] from performing one of its functions
CE marking	The letters 'CE' appear on many products traded on the extended Single Market in the European Economic Area (EEA). They signify that products sold in the EEA have been assessed to meet high safety, health, and environmental protection requirements.
Certification	The provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements, following certain procedures.
Conformity assessment	The process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled (point (12) of Article 2 of Regulation (EC) No 765/2008).
Conformity self-assessment	A conformity assessment performed by the manufacturer without third party involvement. The manufacturer himself or an accredited in-house conformity assessment body that forms a part of the manufacturer's organization, carries out all required controls and checks, establishes the technical documentation and ensures the conformity of the production process.
Cybersecurity	The activities necessary to protect network and information systems, the users of such systems, and other persons affected by cyber threats
Product with digital elements	Hardware and software products which can be directly or indirectly connected to another device or network, as follows: ➢ any device or group of inter–connected or related devices, one or more of which, pursuant to a program, perform automatic processing of digital data.[258] *E.g. end devices such as: laptops, smartphones, sensors and cameras; smart robots; smart cards; smart meters; mobile devices; smart speakers or networks, such as: routers; switches.* ➢ embedded software: Firmware or other software that is essential for the primary function of the end-product and is either: (i) pre-installed in a product; or (ii) separately placed on the market by the manufacturer and downloaded to a product at a later stage. *E.g. firmware, basic operating systems; network system; storage and security management.* ➢ non-embedded software ('standalone' software): Software that is additional to the primary function of the device on which it is downloaded.[259] *E.g. extended operating system, mobile apps.*
Distributed denial-of service (DDoS) attack	A malicious attempt to disrupt the normal traffic of a targeted server, service or network by overwhelming the target or its surrounding infrastructure with a flood of internet traffic.
End of life (of a product with digital elements)	The state of a product having reached the end of its first use until its final disposal.
European cybersecurity certification scheme	According to the *EU Cybersecurity Act,* it means a comprehensive set of rules, technical requirements, standards and procedures that

[258] NIS2 Directive proposal, Article 4(1)(b).

[259] The distinction is in the function of the software: it adds to the basic functionality of the device on which it is downloaded.

	are established at Union level and that apply to the certification or conformity assessment of specific ICT products, ICT services or ICT processes.
Intended purpose	The use for which a product with digital elements is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation
Life cycle (of a product with digital elements)	Consecutive and interlinked stages of a product from first use to final disposal.
New Legislative Framework (NLF)	A framework built on Regulation (EC) No 765/2008 and Decision No 768/2008/EC bringing together all the elements required for a comprehensive regulatory framework to operate effectively for the safety and compliance of industrial products with the requirements adopted to protect the various public interests and for the proper functioning of the single market. The new legislative framework was adopted to improve the internal market for goods and strengthen the conditions for placing a wide range of products on the EU market. It is a package of measures that streamline the obligations of manufacturers, authorised representatives, importers and distributors, improve market surveillance and boost the quality of conformity assessments. It also regulates the use of CE marking and creates a toolbox of measures for use in product legislation. Source: European Commission, Internal Market, Industry, Entrepreneurship and SMEs
Ransomware	Type of malware that prevents or limits users from accessing their system, either by locking the system's screen or by locking the users' files until a ransom is paid
Software Bill of Materials (SBOM)	Document or description that provides details about the components used to build a software application.
Open source project	A project that anybody is free to use, study, modify, and distribute your project for any purpose.
Open source software (OSS)	Software that is distributed with its source code, making it available to anyone and for any purpose with all its rights. It grants users the rights to use, study, change, modify and distribute. Open-source software may be developed in a collaborative public manner.
Placing on the market	The first making available of the product on the Union market.
Making available on the market	Any supply of a product for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.
Small and medium-sized companies	An enterprise that satisfies the criteria laid down in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.05.2003, p. 36): employs fewer than 250 persons, has an annual turnover not exceeding €50 million, and/or an annual balance sheet total not exceeding €43 million.
Standard	A technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory. There could be international, European, harmonized and national standards.

Supply chain	Network between an entity and its suppliers to produce and distribute a specific product or to provide a certain service to the end user.
Supply chain security	Ensuring appropriate measures concerning security-related aspects of the relationship between and entity and its suppliers or service providers. This may entail for an entity to take account of the vulnerabilities specific to each supplier or service providers, the quality of products and cybersecurity practices of their suppliers and service providers, including security development procedures, etc.
Third party conformity assessment	Under the New Legislative Framework, a conformity assessment that requires the intervention of a third party, e.g. an external conformity assessment body (so-called "notified body"). Such a body must be impartial and fully independent from the organisation or the product it assesses.
Users	Companies, public administrations, consumers as well as any other types of entities that deploy and operate products with digital elements, including essential and important entities covered by the revised NIS Directive (such as operators of critical infrastructure).
Vulnerability	Vulnerabilities are weaknesses in the computational logic of a digital system that, once discovered, provide attackers with an opportunity to breach the system. Article 4(8) of the Commission's proposal for a revision of the NIS Directive (COM(2020) 823 final) defines a vulnerability as a *"weakness, susceptibility or flaw of an asset, system, process or control that can be exploited by a cyber threat"*.
Zero-day vulnerabilities	Vulnerabilities discovered by attackers before hardware or software manufacturers become aware of them. As a result, zero-day vulnerabilities can be exploited before the manufacturer has the possibility to develop a fix.

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PART 2/3

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Annexes to the Impact Assessment Report

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020

{COM(2022) 454 final} - {SEC(2022) 321 final} - {SWD(2022) 283 final}

List of Annexes

ANNEX 1: PROCEDURAL INFORMATION

1. Lead DG, Decide Planning/CWP references

Lead DG: Directorate-General for Communications Networks Content and Technology (CNECT).

Decide: PLAN/2022/56.

CWP: Commission Work Programme 2022, Making Europe stronger together (COM(2021) 645 final) under Policy objective A Europe Fit for the Digital Age (initiative number 6).

2. Organisation and timing

The initiative constitutes a core part of the single market and was announced by President von der Leyen in her 2021 State of the Union address. The Commission Work Programme for 2022 envisages the adoption of this Act for Q3 2022 under Policy objective A Europe Fit for the Digital Age (initiative number 6).

It is based on Article 114 TFEU since it aims to improve the functioning of the internal market by setting harmonized cybersecurity rules on all products with digital elements placed on the Union market.

The impact assessment process started with opening of a public consultation and publishing the Call for Evidence for stakeholder comments for a period of 10 weeks from 16 March 2022 until 25 May 2022. For details on the consultation process, see *Annex 2*.

The inter-service group (ISG) met on 28 February 2022 and on 2 June 2022 before submission of the Staff Working Document to the Regulatory Scrutiny Board on 13 June 2022. The ISG consists of representatives of the Secretariat-General, and the Directorates-General CNECT, COMP, JUST, GROW, LS, HOME, SANTE, FISMA, AGRI, JRC, DEFIS, TRADE, ENV, ENER, EMPL, EAC, MOVE, RTD, TAXUD, MARE, EEAS, ECFIN and CLIMA.

3. Consultation of the RSB

On 13 June 2022, the DG CNECT submitted the draft Impact Assessment to the Regulatory Scrutiny Board, in view of a hearing on 6 July 2022.

The Regulatory Scrutiny Board issued a positive opinion with reservations on 8 July 2022.

4. Evidence, sources and quality

The Commission carried out an extensive consultation in preparation of this Impact Assessment report. It benefited from consultation activities already carried out in 2021 for the exploratory study contracted by the Commission and implemented by a consortium made of Wavestone, CEPS, ICF and CARSA to assess the need for horizontal cybersecurity requirements for products with digital elements. To ensure a high level of coherence and comparability of analysis for all potential policy approaches, a second study led by the same consortium was contracted to collect evidence and conduct analyses in the first half of 2022.

In addition to the Commission open public consultation and feedback on the Call for Evidence, the external contractors collected evidence from a variety of stakeholders through targeted interviews with experts covering different domains, focus groups, two workshops and a targeted online consultation. Moreover, to further support evidence based analysis, the Commission has conducted extensive desk research, covering a wide spectrum of policy studies and reports. They have been quoted in the main body of the Impact Assessment.

The quality of the analytical methods is detailed in Section 6 of this report and *Annex 4* below.

ANNEX 2: STAKEHOLDER CONSULTATION (synopsis report)

1. Consultation scope and objectives

The consultation activities aim at collecting the views of Member State competent authorities, Union bodies dealing with cybersecurity, hardware and software manufacturers, importers and distributors of hardware and software, trade associations, researchers and academia, notified bodies and accreditation bodies, cybersecurity industry professionals, consumer organisations and other users of products with digital elements, and citizens. All these different stakeholder groups are expected to have important information and insights as regards possible actions to improve the cybersecurity of products with digital elements, as well as interest in and opinions on shaping the debate about the possible options for the future.

The stakeholder consultation had two objectives:

(1) collect views on the state of cybersecurity as regards products with digital elements,
(2) and collect views on policy options for a future market intervention and their respective impacts.

It will pose general questions designed to collect feedback from the general public and more technical questions targeting expert stakeholders.

The Commission issued the terms of reference for a second study to assist the Commission in evaluating the existing legal and policy framework and to identify policy objectives and propose and assess the expected impacts of a limited number of policy interventions. The second study run for 10 months from February 2022 until December 2022.

Relevant links:

- Study on the need of cybersecurity requirements for ICT products (link)
- Commission Work Programme 2022 (link)
- Call for Evidence for an impact assessment (link)

2. Mapping of stakeholders

The Commission consulted a broad range of stakeholders listed below according to their interest and presumed expertise in the subject matter:

1. **Member State competent authorities** and bodies (such as national cybersecurity authorities).

2. **Union bodies dealing with cybersecurity** such as the EU's cybersecurity agency ENISA (European Union Agency for Cybersecurity) or CERT-EU (Computer Emergency Response Team for the EU Institutions, bodies and agencies).

3. **Hardware and software manufacturers**, including manufacturers of hardware components, ICSs, computers, mobile phones, Internet-of-Things devices, home automation systems, and non-embedded software, such as operating systems or user applications.

4. **Importers and distributors of hardware and software**, which either import products with digital elements from third countries or distribute them throughout the internal market (such as high street retailers and online shops).

5. **Trade associations** representing hardware and software manufacturers but also importers and distributors, such as DIGITALEUROPE, the European DIGITAL SME Alliance, Orgalim, the Information Technology Industry Council (ITI) or the Interactive Software Federation of Europe (ISFE).

6. **Consumer organisations and users of products with digital elements and citizens**, such as the European Consumer Organisation (BEUC), the European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC) and companies, in particular operators of essential services and digital service providers under the NIS Directive in their role as users of products with digital elements.

7. **Researchers and academia** (focussing on those with expertise in secure products with digital elements development life cycles and the design of secure products with digital elements).

8. **Notified bodies and accreditation bodies**, which play an important role in implementing EU product regulations that are based on the NLF.

9. **Cybersecurity industry professionals**, such as pen testers and white hat hackers.

3. Consultation activities

The consultation activities aimed to obtain input on the five main evaluation criteria based on the EU Better Regulation Guidelines (effectiveness, efficiency, relevance, coherence, EU-added value) as well as the potential impacts of possible options for the future. Both the open public consultation and the targeted surveys developed by the study contractor were structured according to the logic of the five criteria.

The following consultation activities were organised:

✓ **A first study:** In December 2021, the Commission has published a study on the need of cybersecurity requirements for products with digital elements[1], which had been conducted by a consortium consisting of ICF, Wavestone, CARSA and CEPS (the exploratory study). The exploratory study has identified several market failures leading to a suboptimal level of cybersecurity of products with digital elements. It has further analysed existing EU and national legislation, and assessed possible regulatory interventions. It concludes that a horizontal legislation laying down requiring across sectors would represent the most cost-effective policy option, creating greater security in the Single Market while enhancing business competitiveness. However, it also concluded that the Commission should perform a more comprehensive and quantitative assessment of the potential policy options.

✓ **An Open Public Consultation** with questions targeting citizens, stakeholders and cybersecurity experts. It included questions regarding the current state of cybersecurity as regards products with digital elements. It focused on policy options for a potential regulatory intervention. The survey contributed to the collection of diverse opinions and experiences from all stakeholder groups. A smaller set of questions was available to all participants. Respondents such as professionals in the field, or organisations with specific knowledge and expertise were directed to respond to a set of targeted questions within the same online survey. The Public Consultation, implemented according to the

[1] https://digital-strategy.ec.europa.eu/en/library/study-need-cybersecurity-requirements-ict-products

Commission's Better Regulation Guidelines for stakeholder consultations, was carried out for a 10-week period, starting in March 2022. The questionnaire was made available in all 24 official EU languages, ensuring that the public consultation is accessible to as many stakeholders as possible, especially citizens.

- ✓ **Surveys** organised by the contractor. An online survey was launched on 16 May 2022 and gathered 24 responses at the time of the finalisation of the impact assessment. The participants were handpicked to cybersecurity experts with an understanding in the areas of cybersecurity public policy, cybersecurity requirements and potential compliance and enforcement costs. The survey was designed to receive detailed feedback on the various aspects of the different policy options, as opposed to the public consultation, the purpose of which was to receive general high-level feedback by a wide range of stakeholders, including non-experts. Participants were presented with the different policy options, and the detailed requirements under policy option 4. Participants were requested to provide cost estimations on compliance and enforcement costs and to provide feedback on the other types of impacts.

- ✓ **Workshops organised by the contractor.** Two workshops have been organised, gathering around 100 representatives from all 27 Member States representing competent authorities, hardware and software manufacturers, importers, distributors, notified bodies, accreditation bodies, and cybersecurity experts. The workshops took place in April and May 2022 and were in addition to the three workshops organised in the framework of the exploratory study.

  - ✓ *Workshop #1* on scope and definitions, policy interplay and cybersecurity requirements. The workshop took place online on 28 April 2022. The study supporting the Commission preparatory work for the upcoming regulatory intervention was presented. In three interactive sessions the scope and definition, policy interplay and cybersecurity requirements were discussed with the stakeholders. 115 people participated, representing industry, governmental agencies, consumer organisations and universities.

  - ✓ *Workshop #2* on risk profiles, conformity assessment procedures and likely impacts. The workshop took place online on 10 May 2022. There were 108 participants. Around half of which represented industry (interests) and around one third represented participants from the public sector across various member states. Other participants included EU agencies, universities and consumer organisations.

    For the respondents, the main driver for a risk categorization (potential physical harm, use, and potential misuse) was dependent on the specific example provided. Most respondents indicated that conformity assessments other than self-assessment could be necessary (84 %). Expected costs as consequences of requirements ranged from “low” for internal product testing/self-assessment, to “high” for security updates and whole life cycle requirements. For all other requirements, “medium” received the most votes.

- ✓ **Expert interviews** were conducted to gain a deeper understanding of current cybersecurity challenges related to products with digital elements, and to discuss policy options for a potential regulatory intervention. The experts were selected by the Commission who also conducted the interviews during the first and second quarters of 2022. Experts included engineers developing digital hardware and software products, professional users, and representative of consumer organisations. This added to the 52 “semi-structured interviews” that were carried out by the exploratory study.

- ✓ **Bilateral discussions with national cybersecurity authorities, the private sector and consumer organisations.** The Commission reached out to national cybersecurity authorities and private sector and consumer representatives during the first and second quarters of 2022.

- ✓ **Reports by the Contractor,** as part of the study supporting the Commission preparatory work for the Cyber Resilience Act.

4. SME test - consultations with SMEs

Additional efforts have been made to gather views from SMEs on the impact of the policy options. However, it has been very difficult to get substantial input from SMEs. SMEs have been included in the consultation activities as follows:

- The initiative was discussed at the SME envoy network and classified as "relevant" on 6 April 2022.[2]

- The public consultation, targeted survey on impacts and workshops have been disseminated through the GROW Small Business Act network of EU SME business associations and the European Enterprise Network (cooperation with GROW A.2. unit). Due to time constraints, it was not possible to carry out a proper SME panel consultation (which requires to be open for 8 weeks, language translations needed, EUsurvey required, and a summary of results after the consultation).

- In addition, DG CNECT presented the initiative at several meetings with various SME associations. For instance: GROW Meeting with SME stakeholders on Wednesday 11 May 2022; Joint conference on 10 May 2022 of the European industry federations Europump (European Pumps Industry Association), CEIR (European Taps and Valves Industry Association) and Pneurop (European compressors, vacuum pumps and pneumatic tools industry association; presentation and discussion of the regulatory intervention at the European Digital SME Alliance working group on cybersecurity on 5 May 2022.

- **Targeted outreach** was done to key SME stakeholders, such as the Digital SME Alliance and their individual members. In the context of the study supporting this report, a targeted list of SMEs was established to be invited to the workshops. In addition, several interviews were done with SMEs related to the impacts of the initiative.

Outcome of the consultation activities:

- In the context of the public consultation, only few individual companies representing SMEs participated (14 in total). This included 7 medium-sized companies (50 to 249 employees), 5 small-sized companies (10 to 49 employees), and 2 micro-sized companies (1 to 9 employees).

- In order to achieve a more representative panel of responses, trade associations representing SMEs have also been considered. In total, 47 organisations

[2] https://ec.europa.eu/docsroom/documents/50041

representing SMEs have been identified, including providers, users, trade associations and other types of companies (e.g. service providers).

- A number of SMEs participated in the workshops: out of the 223 participants in the workshops 1 and 2, 19 participants represented SMEs, including individual companies and trade associations.

5. Consultation webpage & communication activities

Anyone interested was able to provide feedback at different stages of the policy cycle on the Have your say page. Stakeholders that wished to be notified by e-mail on new public consultations could follow the RSS Feed or subscribe to Commission at work – Notifications.

6. Synopsis report of the open public consultation

Profile of respondents

A total of **167 responses to the OPC were received**. Almost two-thirds of responses came from companies/businesses and business associations (35.3% and 28.1% respectively), while 13% of responses came from public authorities. 7.8% of responses came from EU citizens, 2.4% of responses each from consumer organisations and non-governmental organisations (NGOs). 1.8% came from academic/research institutions and 1 response from a trade union. In total, 59 companies/businesses responded. Among them, 45 were large, 7 medium, 5 small, and 2 micro.

Turning to responses received by the country, more than half of the responses came from Belgium (44; 26.3%) and Germany (43; 25.7%) while 22 responses came from non-EU countries (13 from the United States). No responses were received from the following Member States: Croatia, Cyprus, Ireland, Latvia, Lithuania, Luxembourg, Malta, Portugal, Romania, Slovakia, and Slovenia.

Q1: Overall level of cybersecurity of products with digital elements

Respondents were asked to **rank the overall level of cybersecurity of products with digital elements marketed within the European Union** on a scale from 1 to 5 with 5 indicating a very high level of cybersecurity. The majority of respondents (53%) indicated that the overall level of cybersecurity is reflected at level 3, while 23% of respondents indicated level 2 and 12% indicated level 4. There were no significant differences between respondent types.

The majority of large companies (55%) ranked the overall level of cybersecurity of products with digital elements marketed within the European Union with a 3. Medium companies were split, although 43% of their responses also indicated level 3. Among the small and micro companies, level 3 was also reflected in the majority of responses – 50% of micro companies and 40% of small companies. For small companies, the rest of the responses were equally split between levels 1, 2 and 5 (20% each).

Respondents were also asked to elaborate on their answers. Most respondents have stated that **an average level of cybersecurity across all types of products with digital elements is difficult to establish as certain differences can be observed** across sectors, product types or whether they are marketed for businesses or consumers. Several respondents have highlighted **different gaps and obstacles hindering progress** that they observed in the overall level of cybersecurity of products with digital elements. Conversely, several respondents have also indicated **signs of progress and improvements** they observed.

Q2: Level of risk of cybersecurity incidents

Respondents were asked **how the level of risk of cybersecurity incidents affecting products with digital elements has evolved during the last five years**. The majority of respondents (54%) indicated that the risk level has increased significantly and 40% of respondents indicated that the risk level has increased. Only a small minority of respondents (4%) indicated that the risk level has remained the same over the last 5 years and only 1% of respondents mentioned the risk level has decreased significantly. There were no significant differences between respondent types.

The majority of large companies have indicated that the risk level has increased – 38% of them have indicated that the risk level has increased and a further 49% indicated that the risk level has increased significantly. The majority of medium companies (57%) also indicated that the risk level has increased significantly and all (100%) micro companies indicated the same response. Among small companies, the majority of responses indicated that the risk level has increased: 40% indicated the level has increased, and a further 40% indicated that it increased significantly.

Respondents were also asked to elaborate on their answers and they provided various types of **examples of cybersecurity threats that have been observed to increase during recent years**. Several respondents also indicated **underlying causes (e.g. the proliferation of interconnected devices on the market, increased reliance on technology due to remote working, increased sophistication of attacks, geopolitical tensions)** that they think are increasing the risk level of cybersecurity threats. Other respondents have indicated that **the real level of risk is sometimes difficult to assess**.

Q3: Impact of cybersecurity incidents affecting products with digital elements

Respondents were asked to score several **possible consequences of cybersecurity incidents based on their actual negative impact on them or their organisation** by using a scale from 1 to 5 with 5 indicating a very high negative impact. The consequences that have been ranked the highest in terms of their negative impact were ‘reputational damage’ and ‘financial cost of disruption’ (e.g. due to a ransomware attack), as they have both been ranked with an average of 4. However, very close to this level of perceived negative impact were also ‘damage to fundamental rights’ (3.8 average score), ‘financial cost of implementing measures to respond to a cybersecurity incident’ (3.8 average score) and ‘compromising the security of our economy and society’ (3.7 average score). There were no significant differences between respondent types.

Company size breakdown:

5. **The financial cost of implementing measures to respond to a cybersecurity incident:** The majority of large companies (47%) and the majority of medium companies (57%) selected level 4. Micro companies' responses were equally split (50%) between levels 4 and 5, while small companies were also equally split on levels 4 and 5 (40% each), with the rest of 20% of votes being cast to level 3.
6. **The financial cost of disruption (e.g. due to a ransomware attack):** Large companies indicated mixed responses: 31% for level 5, 20% for level 5 and 15% each for levels 2 and 3. The majority of medium companies (43%) indicated level 4, while 40% of small companies indicated and a further 40% of them indicated level 5. Micro companies were equally split (50%) between levels 4 and 5.

7. **Reputational damage:** Most responses from large companies were equally split between levels 3, 4 and 5 (24% each), while only 7% of responses went to each levels 1 and 2. The majority of medium companies (43%) indicated level 4, the majority of small companies were split between levels 4 and 5 (40% each) and micro companies were equally split between levels 4 and 5 as well (50% each).
8. **Compromising the security of our economy and society:** 27% of responses from large companies indicated level 4, 18% the levels 3 and 5 each and only 16% indicated level 2. The majority of medium companies (43%) and all (100%) micro companies indicated level 5 while small companies were equally split between levels 1 to 5 (20% each).
9. **Damage to health and life:** The majority of large companies indicated levels 1 (24%) and 2 (27%). Only 9% indicated levels 5, and 11% indicated each level 3 and 4. Among the medium companies, most responses were received by level 5 (29%). However, 28% of medium companies also refrained from responding here. The majority of small companies (60%) indicated level 2. The rest of the responses were split between levels 1 and 4 (20% each). Micro companies were equally split between levels 3 and 5 (50% each).
10. **Damage to fundamental rights (e.g. privacy, protection of personal data, consumer protection):** Responses from large companies were mixed: most responses from large companies indicated level 4 (22%) and 20% each were allocated to levels 2 and 4, while 16% indicated level 3. The majority of medium companies (43%) indicated level 5, while the majority of small companies (40%) indicated level 3. The remaining responses by small companies were equally split between levels 2, 4 and 5 (20% each). Micro companies were equally split between levels 4 and 5 (50% each).
11. **Environmental damage:** The majority of responses from large companies were split between level 1 (23%) and level 2 (31%). The majority of responses from medium companies were similarly split between levels 1 (28%) and 2 (22%), with a further 14% allocated to level 3. For medium companies, levels 1 and 3 received 19% of responses each. 46% of medium companies refrained from answering this question. Within small companies, 32% indicated level 2 and a further 24% indicated level 1. 40 micro companies did not indicate a level, and among those which did, the most responses went to levels 1 and 4 (16% each).

Respondents were also asked to elaborate their answers. Several stakeholders have indicated that for certain sectors (e.g. healthcare) or certain types of companies (e.g. SMEs) the negative impacts of cybersecurity incidents are more prominent. Other stakeholders have also reiterated the link between the consequences of cybersecurity incidents to their underlying causes or to the circumstances in which they appear. Several stakeholders have also pointed out that certain negative consequences are already covered by existing sectoral legislation.

Q4: Impact on users

Respondents were asked to rank several **impacts on users based on their agreement with the statement** on a scale from 1 to 5 with 5 indicating that they fully agree with it. As a result, respondents indicated that they mostly agree with the fact that the user bears additional costs due to the need to deploy highly-priced technical security solutions (ranked with an average of 4) and with the fact that the user bears the additional cost when affected by a cybersecurity incident (also ranked with an average 4). The statement ‘the user bears additional costs due to highly-priced cybersecurity insurance was ranked slightly lower at

3. There were no significant differences between respondent types. There were no significant differences between respondent types.

Company size breakdown:

- **The user bears the additional cost when affected by a cybersecurity incident:** Most large companies were split between levels 4 (38%) and 5 (33%). Most medium companies were also split between levels 4 (29%) and 5 (29%). The majority of small companies (40%) and all micro companies (100%) indicated level 5.
- **The user bears additional costs due to highly-priced cybersecurity insurance:** Responses from large companies were mixed: 22% indicated level 4, 16% indicated level 5, while 20% indicated level 2 and a further 11% level 3. Among medium companies, most respondents indicated level 3 while levels 2, 4 and 5 received each 14% of responses. The majority of small companies (40%) indicated level 2, while micro companies were equally split (50%) between levels 4 and 5.
- **The user bears additional costs due to the need to deploy highly-priced technical security solutions:** Most responses from large companies were split between levels 3 (22%), 4 (26%) and 5 (27%). Similarly, among medium companies, most responses were split between levels 3 (14%), 4 (29%) and 5 (29%). The highest number of small companies (40%) indicated level 3 while micro companies were equally split (50%) between levels 2 and 5.

Respondents were also asked to elaborate their answers. Several stakeholders detailed their responses by indicating **how the impacts on users differ based on certain specific circumstances** (e.g. whether the user is a consumer or a professional user, the size of the user, type of products with digital elements in case, whether the market is B2B or B2C). Several stakeholders also had **specific comments regarding the cyber insurance market, especially concerning the increased cost of insurance premiums**. Other stakeholders have indicated **additional impacts** (such as the psychological impact or loss of confidence in products with digital elements) that they think will affect the users.

Q5: Awareness and understanding of cybersecurity properties of products with digital elements

Respondents were asked the extent to which they were **aware of the cybersecurity risks associated with products with digital elements** (on a scale from 1 to 5 with 5 indicating that they strongly agreed)**:** 79% declared to be either aware or strongly aware; only 4% were not aware of security risks linked to products with digital elements.

Company breakdown: 75% of large companies agreed with this statement; 48% of medium companies agreed, while 24% were neutral; most (67%) small companies also agreed; micro companies generally agreed (55%); were neutral (10%) and disagreed (25%).

The survey asked whether there is **sufficient and clear information about the cyber security properties of products with digital elements** (on a scale from 1 to 5 with 5 indicating that you strongly agreed)**:** 46% of respondents believed that this was not the case; 33% of them had neutral feelings, while only 17% thought there was enough information.

Large companies generally disagreed (38%) or were neutral (38%); medium companies also disagreed (56%) or were neutral 29%; small companies disagreed (42%) or were neutral (33%); micro companies disagreed (35%) or were neutral (40%).

Respondents were asked about the extent to which **they understood the cybersecurity properties of products and had the skills to operate them securely** (on a scale from 1 to 5 with 5 indicating that they strongly agreed): 64% of them agreed or strongly agreed with this statement; 16% were neutral, and 14% did not believe to understand cyber security properties or have the competencies to use products securely. It has to be specified in this context that even if the percentage of respondents agreeing with this statement is high, it should be interpreted in view of the categories of respondents that were predominantly replying to the public consultation (namely cybersecurity experts) and that only very few citizens participated in the survey.

75% of large companies agreed; medium companies generally agreed (57%) and 24% disagreed; small companies generally agreed (54%), but 29% disagreed.

The survey asked whether respondents **valued products' usability and price over cyber security features** (on a scale from 1 to 5 with 5 indicating that they strongly agreed): 46% of them disagreed with this statement; 33% neither disagreed nor agreed and only 12% seemed to privilege usability and price over cyber security.

Most large companies disagreed (52%) or were neutral (31%); medium companies were mostly neutral (43%) and disagreed (47%); small companies disagreed (42%), were neutral (33%), but also partially agreed (17%); micro companies tended to disagree (30%) or be neutral (40%).

Q6: The role of the manufacturers in addressing cybersecurity vulnerabilities and incidents

Respondents were asked whether **hardware manufacturers were effectively addressing the cybersecurity vulnerabilities and incidents affecting their customers** (on a scale from 1 to 5, with 5 indicating that they strongly agreed): 37% thought this was not the case; 29% were neutral; 28% thought they were being effective.

Company breakdown: large companies mostly disagreed (35%), were neutral (32%) and agreed (29%); medium companies mostly disagreed (50%) or were neutral (27%); small companies mostly disagreed (50%) or were neutral (20%); micro companies generally agreed (50%) or were neutral (25%).

The survey asked the extent to which **software manufacturers were effectively addressing the cybersecurity vulnerabilities and incidents affecting their customers** (on a scale from 1 to 5, with 5 indicating that they strongly agreed): 33% disagreed or strongly disagreed software manufacturers were effectively doing it; 30% were neutral, and 34% believed they were instead effective.

Large companies disagreed (35%) or agreed (35%); medium companies disagreed (32%), were neutral (27%) or disagreed (27%); small companies disagreed (37%) or were neutral (33%) and only some agreed (21%); micro companies mostly agreed (45%) or were neutral (25%).

Q7: Aspects having the biggest impact on manufacturers' decisions related to cybersecurity of products with digital elements

Most manufacturers (65%) reported that **the potential reputational damage and the loss of users' trust following an incident** were very relevant factors in their decision-making regarding the cyber security of their products with digital elements.

74% of large companies thought it was very relevant, compared to 36% of medium enterprises; 47% of small companies believed it was relevant too, compared to 93% of micro companies.

Most manufacturers (77%) declared that **customer expectations, including contractual obligations**, were either relevant or very relevant in their decision-making regarding the cybersecurity of their products with digital elements; 20% did not have an opinion about it.

Companies opted for either relevant or very relevant: large (84%); medium (64%); small (65%) or micro (93%).

Most manufacturers (66%) agreed or strongly agreed that **public procurement practices** had a big impact on their decision making regarding the cybersecurity of their products with digital elements; 24% did not know.

Companies opted for either relevant or very relevant: large (72%), medium (36%), small (58%) and micro (86%).

Respondents also pointed out **other aspects which influence their decision-making regarding the cyber security of products with digital elements**, including (ranked based on frequency, from most to least mentioned): threat scenario (i.e. cyber security risks and attack vectors); type and intended use of the product; general security standards and requirements, deriving from compliance, legislation and best practices; safety concerns; other requirements, such as usability and interoperability; supply chain; production, operation, and maintenance costs.

Q8: Cybersecurity of products with digital elements in the product life cycle

Respondents were asked **the extent to which hardware and software manufacturers took the cybersecurity of their products with digital elements into account in the design phase** (on a scale from 1 to 5 with 5 indicating that cybersecurity is taken very seriously) of a product life cycle and the results ranged mainly from not seriously (29%), neutral (19%) and seriously (21%).

Large companies thought it was taken seriously (40%) but also not seriously (33%); most medium companies (52%) believed it was not taken seriously; most small companies were neutral (27%) or thought it was not taken seriously (36%); 48% of micro companies believed it was taken seriously.

Respondents were asked **the extent to which hardware and software manufacturers took the cybersecurity of their products with digital elements into account in the development phase** (on a scale from 1 to 5 with 5 indicating that cybersecurity is taken very seriously) of a product life cycle and the results ranged mainly from not seriously (25%), neutral (26%) and seriously (19%); an additional 16% thought that these are taken very seriously.

Large companies generally indicated it was taken seriously (42%) or not taken seriously (32%); medium companies thought it was not taken seriously (47%) or were neutral (19%); small companies believed it was taken seriously (33%) and not seriously (29%).

Respondents were asked about **the extent to which hardware and software manufacturers took the cybersecurity of their products with digital elements into account during the release of the product on the market phase** (on a scale from 1 to 5 with 5 indicating that cybersecurity is taken very seriously) of a product life cycle and results ranged mainly from not seriously (25%), neutral (26%) and seriously (21%).

34% of large companies thought it was taken seriously and 29% were neutral; 47% of medium companies believed it was not taken seriously; 36% of medium companies were neutral and 27% thought it was not taken seriously; 47% of micro companies believed it was taken seriously and 14 were neutral.

Respondents were asked **the extent to which hardware and software manufacturers took the cybersecurity of their products with digital elements into account after the release of a product, namely maintenance and evolution of the product phase** (on a scale from 1 to 5 with 5 indicating that cybersecurity is taken very seriously), and results ranged mainly from not seriously (24%), neutral (32%) and seriously/very seriously (27%).

Companies of all sizes were generally neutral or tended to think it was not taken seriously: large (37%); medium (47%), and small (27%). Only micro companies thought it was taken seriously (33%) compared to non-seriously (14%).

Q9: Effectiveness of measures to increase cyber security of products with digital elements

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure would be very effective) **guidelines or recommendations for the development of secure products with digital elements issued at the EU level addressed to manufacturers** could be effective in increasing the cybersecurity of products with digital elements marketed in the EU: almost half (47%) agreed these could be effective, while 27% were neutral; 25% did not believe these measures would be effective.

Companies of all sizes tended to think these could be effective: large (49%); medium (29%), small (45%) and micro (59%) or were generally neutral (respectively, 20%, 38%, 46% and 23%).

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure would be very effective) **further voluntary European cybersecurity certification schemes** for products with digital elements and services could be effective in increasing the cybersecurity of products with digital elements marketed in the EU: 37% disagreed these could be effective; 31% were neutral, and 31% agreed these measures would be effective.

40% of large and 46% of medium companies stated they could be effective; 33% of small companies thought they could be effective and the same percentage believed the opposite; micro companies were mainly neutral (36%) or thought they could be effective.

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure would be very effective) **EU public procurement guidelines** taking into account cybersecurity requirements could be effective in increasing the cybersecurity of products with digital elements marketed in the EU: 60% agreed these could be effective; 28% were neutral; 9% disagreed these measures would be effective.

Most companies gave neutral answers or tended to agree these could be effective: large (56%); medium (63%), small (58%) and micro (55%).

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure would be very effective) **amending existing legislation regulating specific products with a digital dimension** (such as the legislation on lifts or gas appliances) could be effective in increasing the cybersecurity of products with digital elements marketed in the EU: 51% agreed these could be effective; 17% were neutral; 27% disagreed these measures would be effective.

55% of large companies believed it could be effective and so did 54% of medium ones; small companies had mixed feelings but 46% also believed they could be effective; 36% of micro companies instead declared these might not be effective or were neutral about it (31%).

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure would be very effective) **introducing mandatory horizontal cybersecurity requirements for <u>hardware products</u>** could be effective in increasing the cybersecurity of products with digital elements marketed in the EU: 72% agreed these could be effective; 13% were neutral; 10% disagreed these measures would be effective.

Most companies of all sizes thought these could be effective, namely large (73%), medium (71%), small (67%) and micro (81%).

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure would be very effective) **introducing mandatory horizontal cybersecurity requirements for <u>software products</u>** could be effective in increasing the cybersecurity of products with digital elements marketed in the EU: similarly to the question above, 74% agreed these could be effective; 10% were neutral; 11% disagreed these measures would be effective.

Most companies of all sizes believed these could be effective, namely large (76%), medium (71%), small (81%) and micro (66%).

When asked to elaborate on their answers, respondents highlighted the following themes: Mandatory **horizontal legislation is the preferred option** vs "softer" approaches (as already found in the survey above); Requirements must be **clear as well as limit fragmentation/duplication**; Alignments with **existing legal instruments**.

Q10: Requiring manufacturers to act

Respondents were asked to assess the impact (on a scale from 1 to 5 with 5 indicating that a measure would have a very high impact) of **requiring manufacturers to make available information and provide instructions on securely installing, operating and using the product** in question: 70% reported this would have a high or very high impact; 22% were neutral, and 8% suggested this would have a low or very low impact.

Most companies of all sizes thought this could have a high impact, namely large (71%), medium (67%), small (54%) and micro (90%).

Respondents were asked to assess the impact (on a scale from 1 to 5 with 5 indicating that a measure would have a very high impact) of **requiring manufacturers to take corrective actions** (such as patching, recalling or withdrawing a product) when a product is found to be not secure: 86% reported this would have a high or very high impact; 7% were neutral and 7% suggested this would have a low or very low impact.

Most companies of all sizes thought this could have a high impact, namely large (83%), medium (88%), small (83%) and micro (95%).

Q11: Relevance of cyber security measures to users

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure is very relevant) making available **technical documentation** (containing information to demonstrate the conformity of the product to the applicable requirements) on the cybersecurity properties of a product (such as on risks and proper use) would help users assess cybersecurity properties of products with digital elements: 47% reported this would be relevant or very relevant; 26% were neutral and 25% suggested this would not be relevant.

Companies of all sizes generally thought this could be relevant, namely large (49%), medium (46%), and micro (55%); small companies were mostly neutral (39%).

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure is very relevant) making available an **EU Declaration of conformity** (stating that all the relevant requirements of the applicable legislation are satisfied) would help users assess cybersecurity properties of products with digital elements: 51% reported this would be relevant or very relevant; 25% were neutral and 19% suggested this would not be relevant.

Companies were either neutral or tended to agree this could be relevant, namely large (57%), medium (33%), small (46%) and micro (41%).

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure is very relevant) **affixing a symbol of compliance** such as CE marking would help users assess the cybersecurity properties of products with digital elements: 51% reported this would be relevant or very relevant; 22% were neutral and 22% suggested this would not be relevant.

Most large (57%), small (50%) and micro (41%) companies stated this could be relevant; medium ones instead either disagreed (38%) or were neutral (29%).

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that a measure is very relevant) **training on the secure use of products with digital elements** would help users assess the cybersecurity properties of products with digital elements: 57% reported this would be relevant or very relevant; 23% were neutral and 17% suggested this would not be relevant.

Most companies of all sizes declared this could be effective, namely large (50%), medium (54%), small (63%) and micro (73%).

Respondents elaborated upon their answers and highlighted the following themes: Equipping users with the right cyber security knowledge; Security information provided to users should be easy and understandable; Be clear about the expected lifetime of a product and consequential security updates; A symbol/label of compliance could also be useful.

Q12: Effectiveness of cyber security requirements subjecting different products and services

Respondents were asked the extent to which (on a scale from 1 to 5 with 5 indicating that they strongly agreed) they believed **subjecting hardware products** marketed in the EU to cybersecurity requirements would be an effective measure: 67% either agreed or strongly agreed; 16% were neutral and 10% either disagreed or strongly disagreed.

Most companies of all sizes declared this could be effective, namely large (65%), medium (58%), small (60%) and micro (56%).

Respondents were asked the extent to which (on a scale from 1 to 5 with 5 indicating that they strongly agreed) they believed **subjecting embedded software** marketed in the EU to cybersecurity requirements would be an effective measure: 77% either agreed or strongly agreed; 9% were neutral and 9% either disagreed or strongly disagreed.

Most companies of all sizes declared this could be effective, namely large (77%), medium (83%), small (79%) and micro (59%).

Most companies of all sizes declared this could be effective, namely large (57%), medium (54%), small (63%) and micro (59%).

Respondents were asked the extent to which (on a scale from 1 to 5 with 5 indicating that they strongly agreed) they believed **subjecting hardware products with higher cybersecurity risks** marketed in the EU to cybersecurity requirements would be an effective measure: 85% either agreed or strongly agreed; 4% were neutral and 4% either disagreed or strongly disagreed.

Most companies of all sizes declared this could be effective, namely large (82%), medium (88%), small (83%) and micro (86%).

Respondents were asked the extent to which (on a scale from 1 to 5 with 5 indicating that they strongly agreed) they believed **subjecting all standalone software products** marketed in the EU to cybersecurity requirements would be an effective measure: 58% either agreed or strongly agreed; 19% were neutral and 16% either disagreed or strongly disagreed.

Most companies of all sizes declared this could be effective, namely large (59%), medium (54%), small (63%) and micro (56%).

Respondents were asked the extent to which (on a scale from 1 to 5 with 5 indicating that they strongly agreed) they believed **subjecting software products subject to higher cybersecurity risk** marketed in the EU to cybersecurity requirements would be an effective measure: 86% either agreed or strongly agreed; 18% were neutral and 5% either disagreed or strongly disagreed.

Most companies of all sizes declared this could be effective, namely large (84%), medium (92%), small (83%) and micro (82%).

Respondents elaborated upon their answers and highlighted the following topics: Any EU legislation should adopt a **risk-based approach**; The importance of **clear definitions and scope**.

Q13: Appropriateness of existing EU regulation

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that they strongly agreed with a statement) existing EU regulations appropriately addressed cybersecurity of **tangible products with digital elements** (hardware) throughout their life cycle: 41% of respondents either strongly disagreed or disagreed; 28% were neutral and 13% either agreed or strongly agreed.

Large companies selected 3 (33%) and 2 (24%). Medium companies opted for 2 (67%). Small companies were divided into 1, 2, 3 and 5 (20% for each). Micro companies were evenly split between 3 and 4.

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that they strongly agreed with a statement) existing EU regulation appropriately addressed cybersecurity of **intangible products with digital elements (software)** throughout their life cycle: 46% of respondents either strongly disagreed or disagreed; 28% were neutral and 12% either agreed or strongly agreed.

Large companies opted for 2 (33%) and 3 (31%). Medium companies chose 2 (50%), while small companies 1 (40%). Micro companies were evenly split between 3 and 5.

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating that they strongly agreed with a statement) existing EU regulation appropriately addressed **all relevant cybersecurity risks (material and non-material damages) related to the use or misuse of a product with digital elements**: 43% of respondents either strongly disagreed or disagreed; 25% were neutral, and 15% either agreed or strongly agreed.

Large companies chose 3 (32%) and 2 (22%), while 50% of Medium companies opted for 2. Small companies were divided for all responses (20% each), except for 2. Micro companies were equally divided between 2 and 5.

Q14: Risk of increasing costs and legal uncertainty in the absence of an EU initiative

The survey asked the extent to which (on a scale from 1 to 5 with 5 indicating they fully agreed) there was a **risk of increasing costs and legal uncertainty for market stakeholders in the absence of an EU initiative**, namely in a scenario in which the Member States could adopt national laws placing certain requirements on manufacturers as opposed to horizontal cybersecurity requirements at European level: 85% either agreed or strongly agreed; 9% were neutral and 4% either disagreed or strongly disagreed.

Most companies of all sizes declared this could be effective, namely large (86%), medium (83%), small (92%) and micro (86%).

Respondents elaborated upon their answers and almost unanimously concluded that an **EU-wide initiative was to be preferred** compared to single initiatives at the member state level.

Q15: Legal requirements related to the cybersecurity of products with digital elements for manufacturers

Respondents who identify as manufacturers were asked to respond whether their products with digital elements are subject to **legal requirements as regards their cybersecurity**. They were also advised to take into account in their answer European, national but also legislation stemming from third countries. The majority of respondents who replied to this question (65%) indicated that their products with digital elements are subject to legal requirements as regards their cybersecurity, while only 3% indicated the opposite. Out of the 65% of respondents who indicated 'yes', the vast majority were represented by business associations (25% of responses) and companies/business organisations (37% of responses).

The majority of large companies (67%) indicated that their products with digital elements are subject to legal requirements as regards their cybersecurity. 28% of medium companies also responded positively although 43% indicated that they are not concerned by this question and a further 29% did not respond. The majority of small companies (60%) and 50% of micro companies also responded although the other 50% of micro companies did not provide an answer.

Respondents were also asked to indicate **which of their products with digital elements are subject to which legal requirements as regards their cybersecurity and to specify the relevant product categories and applicable legislation**. The following categories of products were mentioned together with the applicable legislation: information and communications technology (ICT) products, services, and processes – are subject to certification frameworks under the Cybersecurity Act (EU/2019/881); radio equipment (electrical and electronic equipment that can use the radio spectrum for communication and/or radio determination) - is subject to Radio Equipment Directive. The proposed delegated act (2021) expands that scope from smart appliances and cameras to connected radio equipment like cell phones, laptops, alarm systems, wearable health monitoring devices, home automation, and other internet-connected devices; digital services providers (online search engines, online marketplaces, and cloud computing services) – are subject to the security of the Network and Information Systems Directive (NIS 2.0); motor vehicles – are subject to Regulation 2018/858 on type approval for motor vehicles; Regulation (EU) 2019/2144 (General Safety Regulation), and UN Regulation 155 on uniform provisions concerning the approval of vehicles with regards to cyber security and cyber security management system; UN Regulation 156 on software updates and software management system; Regulation 2014/53 Radio Equipment Directive (for radio equipment of motor vehicles); medical products – subject to Medical Device Regulation, In-Vitro Diagnostic Regulation, Machinery Directive, General Product Safety Directive, Radio-Equipment Directive (RED-DR not for MDR/IVDR products but in scope for accessories and non-medical products); financial products – subject to PSD2, EBA-Guidelines, requirements of the European Central Bank, NIS-Directive, future Digital Operational Resilience Act (DORA), BSI Act (BSIG), Prudential requirements for IT (BAIT).

Other types of horizontal legislation (from the EU and third countries) mentioned by several stakeholders were: the EU's General Data Protection Regulation – which covers the requirements related to protecting data, and breach reporting; the California Consumer Privacy Act and California IoT Cybersecurity Law; products in the scope of the Sales of Goods Directive (EU) 2019/771 need to provide security updates; the 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 information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act).

Q16: Responsibility of hardware and software manufacturers

Respondents were asked whether **hardware and software manufacturers should be responsible for the full life cycle of a product with digital elements** (such as by being required to provide updates). The vast majority of respondents (88%) indicated a positive answer to the question, while only 9% indicated a negative one. There were no significant differences between respondent types.

Responses were in their majority affirmative for all sizes of companies: 80% of large companies, 86% of medium companies and 100% of both small and micro companies.

Respondents who indicated that hardware and software manufacturers should be required to provide security updates were also asked for **how many years should they be required to do so**. Most respondents (13%) who provided several fixed numbers of years for this obligation indicated 5 years as the ideal period for which hardware and software manufacturers should be required to provide security updates. 9% of respondents also indicated 10 years as their ideal timeframe, while only 7% of respondents indicated a lower timeframe of 3 years.

Most large companies refrained from responding (40%) or preferred to provide other responses than the ones indicated (40%). Likewise, 60% of small companies preferred to offer another response. The same applies to medium companies as 43% did not respond and 29% did not know or had no opinion. However, 14% each indicated 3 and 4 years as their responses. Micro companies' responses were equally split between 1 and 10 years.

The majority of stakeholders (51%) who responded to this question chose to detail their response rather than pick a fixed number of years. Several responses indicated that the **obligation should exist for the entire life cycle** of the hardware/software product. A few responses also **disagreed** with the idea of an obligation that would exist throughout the entire life cycle of the hardware/software product. Others stressed that **the timeframe of the obligation should be adapted** based on the type of hardware/software product provided or other specific circumstances. Others stressed that **providing updates is not sufficient**.

Q17: Approaches contributing to the cybersecurity of a product with digital elements

Respondents were asked to rank **to what extent several approaches contribute to the cybersecurity of a product with digital elements** by using a scale from 1 to 5 with 5 indicating that the measure would be very effective. The measure deemed most effective and which received the higher score (4.8) was the measure indicating that 'cybersecurity is taken into account during all phases of the development process (security by design)'. The next best average score was 4.7 and was awarded by respondents to the measure stipulating that 'Hardware and software manufacturers provide updates when vulnerabilities are discovered, including after a product has been put on the market'. At the other end of the spectrum, the measure deemed least effective and which received the lowest score (3.3) stipulated that 'Hardware and software manufacturers should make available to relevant stakeholders (e.g. end-users) a list containing the details and supply chain relationships of various components used in building the product with digital elements (so-called Software Bill of Materials)'. There were no significant differences between respondent types.

Respondents were also asked to indicate which **other measures taken by hardware and software** manufacturers **could improve the cybersecurity of products with digital elements**. Among the additional measures that have been indicated were: the utilisation of strong technical protection mechanisms, including encryption; an improved mechanism for assistance from national security/cybersecurity authorities to help the private sector address dynamic cybersecurity risks; continuous education, training and assessment of the personnel of the organization to the specific requirements, implementation mechanisms, secure coding principles, etc.; manufacturers must be required to effectively communicate the supply chain relationship of the myriad of components, from different hardware and software manufacturers , that make up the IoT device; manufacturers should assure the robustness of their software/service towards ransomware attacks. For instance, measures that protect already stored backups from being modified, requiring multi-factor authentication for access to backup infrastructures, requiring separate authentication for application management and backup infrastructure management, penetration testing backup infrastructure annually, testing reinstallation of backups periodically etc.; training of consumers, especially vulnerable consumers; the adoption of bug bounty programs; open-source approach/sources open and auditable; commitment to the Digital Responsibility Goals; for the critical software/hardware products, periodic recertification/testing of software and hardware products by independent 3rd parties and government entities.

Q18: Approaches regarding higher risk products with digital elements

Respondents were asked **whether products with digital elements with a higher risk should be subject to a stricter process of demonstrating conformity with cybersecurity requirements**. The vast majority of respondents (88%) indicated an affirmative answer while only a small minority (5%) disagreed. There were no significant differences between respondent types.

Companies of all sizes also overwhelmingly responded yes: large (84%), medium (83%), small (100%) and micro (100.00%).

Respondents were also asked to indicate **what would be the categories of risk that a risk-based methodology should take into account when hardware and software manufacturers would be required to demonstrate their compliance with cybersecurity requirements**. A large majority of responses (87%) indicated that a risk-based methodology should include 'the intended use of a product (such as for the provision of health services, as an industrial control system or in a safety context)'. A slightly lower share of responses (83%) also indicated that the methodology should include 'the functionality of a product (such as whether it has a network interface or not, or whether it controls certain security features of a digital system)'. On the other hand, only 44% of responses stressed the need to include 'the societal importance of a product (for example measured in market share or number of users)'.

Similarly, companies of all sizes prioritise the functionality and the intended use of a product.

Within the responses received from respondents who wished to elaborate, it was observed that several respondents expressed their concerns about the definition of high-risk categories or their view that a case-by-case analysis would be more appropriate.

Other respondents raised new aspects that should also be taken into account when developing risk methodologies: a potential stricter process of demonstrating conformity should take into consideration the respective sector in which the product is to be deployed; not only the vulnerability itself but also the exploitability is important. Hence, market share and the number of users counts; the impact of a product on the continuity of the operation (i.a. how deeply it is intertwined with other systems) should also be taken into account; the New Legislative Framework (NLF) has proven to be highly effective in addressing different risk levels of products, e.g. with different modules provided as the basis for conformity assessment procedures and determination of the appropriate risk. This should be applied in the same way in the case of cybersecurity; the larger the market share, the greater the range for cyber attacks (potential victims); the risks to rights and freedoms of individuals (not covered by the "societal importance" risk category above).

Respondents were asked **who should determine the risk associated with a product and, as a result, its risk categorisation**. The majority of respondents (52%) indicated that risks and risks categorisation should be determined by 'an independent body responsible for verifying compliance with the cybersecurity requirements' while 'a competent authority' was indicated by 39% of respondents.

Similarly, most companies of all sizes chose the same answer, in addition to indicating that manufacturers should also be involved.

Among the respondents who chose to elaborate their answer or to provide a different answer, a few indicated other actors that should be involved in the determination of risk and risk categorisation: an independent body responsible for standardisation like ISO IEC for critical components; the user/customer; the risk associated with a product and, as a result, its risk categorization should be developed jointly in a multi-stakeholder approach.

Q19: Self-declaration

Respondents were asked to assess **if a self-declaration of conformity by a hardware or software manufacturer gives sufficient confidence that security requirements are met** (on a scale from 1 to 5 with 5 indicating that you strongly agree). Most of all respondents responded with 2 (28%), followed by 3 (23%). The response from companies was more positive, with 27% choosing 3, and 23% responding 5.

Most large companies responded with 3 (33%), followed by 2 (19%), and medium companies with 2 (33%). Small companies were equally split between 1 and 5 (40% each), while the two Micro companies were between 2 and 5.

Q20: Third-party verification

Respondents were **asked if they consider that self-declaration is not enough to demonstrate compliance with security requirements, do they think that the involvement of a third party should be required under certain circumstances**. Most respondents answered yes (79%), 13% answered no, while 8% didn't know. There was no difference between the respondent groups.

The majority of large (83%), medium (80%), small (100%) and micro (100%) companies also answered yes.

Respondents were asked **under which circumstances should third-party verification apply**. Most respondents answered that if a product presents a higher risk (68%).

The majority of large (63%), medium (50%), small (100%) and micro (100%) companies agreed.

Those that responded "other" were asked to elaborate. While some respondents thought that self-assessment can be sufficient (in combination with standards, market surveillance and the disciplining effect of the market), nevertheless clear majority said that third-party verification is needed, especially for higher-risk products to ensure compliance, objectivity and accountability.

Q21: Effectiveness of horizontal requirements

Respondents were asked to what extent they agree **that cyber risks can propagate across borders and sectors at high speed, which is why cybersecurity rules for products with digital elements should be aligned at the Union level**. Most respondents strongly agreed (71%) and agreed (21%). There was no difference among the respondent types.

The majority of large (70%), medium (83%), small (60%) and micro (100%) companies also strongly agreed.

Respondents were asked to what extent they agree that **horizontal cybersecurity requirements for products with digital elements would increase the awareness of users when it comes to cyber risks**. Most respondents agreed (54%) and strongly agreed (24). There was no difference among the respondent types.

Large companies agreed (51%) and strongly agreed (24%). Medium companies strongly agreed (50%). 40% of small companies disagreed, while the rest of the responses were split between all the other responses. 100% of Micro companies strongly agreed.

Respondents were asked to what extent they agree **that horizontal cybersecurity requirements for products with digital elements would enhance and ensure a consistently high level of the security of products with digital elements**. Most respondents agreed (43%) and strongly agreed (42%). There was no difference among the respondent types.

Large companies strongly agreed (45%) and agreed (33%). Medium companies strongly agreed (67%). Small companies strongly agreed (40%) and agreed (20%). Micro companies strongly agreed (100%).

Respondents were asked to what extent they agree that **horizontal cybersecurity requirements would improve the functioning of the internal market by levelling the playing field for manufacturers of products with digital elements as regards cybersecurity features**. Most respondents strongly agreed (47%) and agreed (34%). There was no difference among the respondent types.

Large companies agreed (40%) and strongly agreed (36%) Medium companies strongly agreed (67%). Small companies were split between strongly agreeing (40%) and strongly disagreeing (40%). Micro companies strongly agreed (100%).

Q22: Horizontal requirements for digital dual-use products

The EU Action Plan on synergies between civil, defence and space industries underlines the importance of promoting and applying common standards across sectors and the increased relevance of products with digital elements that are used both in a civilian and military context ('dual-use products').

Respondents were asked **to what extent could horizontal requirements applying to digital dual-use products contribute to moving the security performance of such products closer to the needs of the defence community and to raising the overall level of cybersecurity in civilian uses** (on a scale from 1 to 5 with 5 indicating a very positive contribution). Most respondents did not know/had no opinion (47%). Among those who had, most selected 4 and 5 (16% each).

Large companies didn't know/had no opinion (48%), followed by 4 (17%). Medium companies chose 4 and 5 (33% each). Small companies indicated 3 (50%), and the rest were split between 2 and 5 (25% each). Micro companies were split between 1 and 5.

Respondents were asked to elaborate. Some respondents with caveats, but **in general agreed with the question**. Some expressed **scepticism and stressed the differences between the sectors, differing security requirements and potential price increases for consumers**.

Q23: The impact on costs

Respondents were asked to assess the impact of **guidelines or recommendations for the development of secure products with digital elements issued at the EU level addressed to manufacturers** on their costs (on a scale from 1 to 5 with 5 indicating that the intervention would be very costly). Most large companies (49%) responded that the impact on costs will be 2. The responses from medium companies were mixed and equally distributed across 1 and 5 (20%). Most small companies (40%) responded that the impact on costs will be 4. The response from two Micro companies was mixed, equally distributed between 1 and 5.

Respondents were asked to assess the impact of **further voluntary European cybersecurity certification schemes for products with digital elements and services** on their costs (on a scale from 1 to 5 with 5 indicating that the intervention would be very costly). The majority of large (47%), medium (60%) and small (40%) companies responded that the impact on costs will be 3. The response from two micro companies was mixed, equally distributed between 2 and 5.

Respondents were asked to assess the impact of **EU public procurement guidelines taking into account cybersecurity requirements** on their costs (on a scale from 1 to 5 with 5 indicating that the intervention would be very costly). Most large companies (28%) responded 2. Most medium companies (60%) responded 3. Small companies were divided between 2 (40%) and 3 (40%), while two micro companies were between 1 and 5.

Respondents were asked to assess the impact of **amending existing legislation regulating specific products with a digital dimension (such as the legislation on lifts or gas appliances)** on their costs (on a scale from 1 to 5 with 5 indicating that the intervention would be very costly). Companies of all sizes provided equally split responses, with large companies between 4 (28%) and "Don't know/no opinion" (28%), medium companies between 3 (40%) and 5 (40%), small companies between 1 (40%) and "Don't know/no opinion" (40%), and two micro companies between 1 and 5.

Respondents were asked to assess the impact of **introducing mandatory horizontal cybersecurity requirements for hardware products** on their costs (on a scale from 1 to 5 with 5 indicating that the intervention would be very costly). Large companies' responses closely clustered around 3 (26%) and 4 (23%). Most medium companies responded with 3 (40%), while most small companies indicated 1 (40%). Two micro companies were split equally between 1 and 5.

Respondents were asked to assess the impact of **introducing mandatory horizontal cybersecurity requirements for software products** on their costs (on a scale from 1 to 5 with 5 indicating that the intervention would be very costly). Large companies responded closely between 3 (26%), 4 (23%), 5 (25%). Medium companies were split between 3 (40%) and 5 (40%). Most small companies responded with 1 (40%), while two micro companies were split between 2 and 5.

Respondents were asked to elaborate on their answers, by quantifying the costs if possible. Multiple respondents noted that it is **difficult to quantify and provide costs**. Several respondents noted that the **benefits will likely outweigh the costs**. Most stakeholders who provided written responses expressed overall **support for the horizontal requirements**. Conversely, multiple stakeholders expressed the **dangers of legislative fragmentation**.

Q24: Proportionate obligations for SMEs

Respondents were asked **if subjecting SMEs to the same obligations as larger companies would ensure that SME hardware and software manufacturers, including individual entrepreneurs, are subject to proportionate obligations (balance between administrative burden and compliance costs on the one hand and a high level of cybersecurity on the other hand) under European legislation introducing mandatory horizontal cybersecurity requirements** (on a scale from 1 to 5 with 5 indicating that you strongly agree with a statement). Large companies responded with 4 (30%) and 5 (21%). Most medium and small companies chose 5 (40% within each size category). Two micro companies were split between 4 and 5.

Respondents were asked **if introducing simplified procedures to demonstrate conformity for SMEs and individual entrepreneurs would ensure that SME hardware and software manufacturers, including individual entrepreneurs, are subject to proportionate obligations (balance between administrative burden and compliance costs on the one hand and a high level of cybersecurity on the other hand)**

under European legislation introducing mandatory horizontal cybersecurity requirements (on a scale from 1 to 5 with 5 indicating that you strongly agree with a statement). Most large companies responded with 4 (24%) and 3 (20%). Medium companies were equally divided between all 5 responses (17% per each response). Small companies were divided between 2 and 5 (20% per response). Two micro companies chose 5.

Respondents were asked to elaborate on which other approaches could ensure proportionate obligations vis-à-vis SME hardware and software manufacturers, including individual entrepreneurs. Several respondents suggested reducing the cost of/simplifying assessment and certification. Several respondents stressed that obligations should be based on the criticality of the product rather than the company size. Several respondents discussed horizontal regulation as a solution.

Q25: The impact on competition

Respondents were asked **if mandatory cybersecurity requirements will put smaller hardware and software manufacturers at a disadvantage compared with larger competitors** (on a scale from 1 to 5 with 5 indicating that you strongly agree with a statement). Large companies responded 4 (30%) and 2 (23%). Medium companies were split between 1 and 2 (30% per response). Most small companies chose 1. Two micro companies were split between 2 and 5.

Respondents were asked **if mandatory cybersecurity requirements will put EU hardware and software manufacturers at a disadvantage in the non-EU markets compared to non-EU competitors that are not subject to such requirements** (on a scale from 1 to 5 with 5 indicating that you strongly agree with a statement). Large companies chose 2 (33%) and 1 (21%). Most medium companies responded 2 (50%). Small companies we divided between 1 and 3 (40% each), while two Micro companies between 1 and 5.

Q26: The impact on fundamental rights

Respondents were asked **if horizontal cybersecurity requirements for products with digital elements would enhance the protection of privacy and personal data** (on a scale from 1 to 5 with 5 indicating that you strongly agree with a statement). Most respondents selected 5 (41%), followed by 4 (32%). There were no outliers among the different types of respondents. Large companies chose 5 (42%) and 4 (33%). Medium companies selected 5 (50%) and 3 (33%). Small companies indicated 3 (40%) and the rest were split between 4 and 5 (20% each). Micro companies chose 5 (100%).

Respondents were asked **if horizontal cybersecurity requirements for products with digital elements would ensure a high level of consumer protection** (on a scale from 1 to 5 with 5 indicating that you strongly agree with a statement). Most respondents chose 4 (38%), followed by 5 (36%). There were no outliers among the different types of respondents. Large companies chose 5 (42%) and 4 (35%). Medium companies selected 5 (65%). Small companies indicated 3 (40%) and the rest were split between 4 and 5 (20% each). Micro companies chose 5 (100%).

Q27: Other challenges

Respondents were asked to elaborate if in addition to the issues above, are there other cybersecurity-related challenges not directly linked to the cybersecurity of products that the Cyber Resilience Act should include to enhance the cyber resilience of the internal market. Multiple stakeholders stressed end-user education/responsibility, digital literacy, skills and training. Multiple respondents discussed the need to ensure legislative coherence and avoid duplication and fragmentation. Related to this, some respondents want to narrow the scope of the CRA. Several respondents discussed sector-specific solutions.

ANNEX 3: WHO IS AFFECTED AND HOW?

The following stakeholders would be mainly affected by the initiative:

- Software manufacturers
- Hardware manufacturers
- Importers of products with digital elements
- Distributers of products with digital elements
- End-users, including businesses, public authorities and consumers
- Market surveillance authorities
- Accreditation and notifying authorities
- Notified bodies

The initiative would broadly and most significantly impact the EU software and hardware market. A high-level market overview has been provided in *section 5.1.1*. This Annex includes a more a detailed overview of the **market players** that would be affected by the initiative developed by the supporting study[3], and the **overview of aggregated costs and benefits for the preferred policy option**.

1. Market Analysis: hardware and software manufacturers

The EU software market

Methodology

Based on the data gathered by a recent study which provided for a breakdown of the software and software-based services market,[4] the following categories can be identified: (1) **Software products**;[5] (2) **Software-related services**;[6] (3) **Cloud computing**;[7] (4) **Games.**

[3] Second Interim Study Report N° 2019-0024 supporting the impact assessment

[4] https://op.europa.eu/en/publication-detail/-/publication/480eff53-0495-11e7-8a35-01aa75ed71a1

[5] including infrastructure software & platforms, application software products; excluding SaaS.

[6] including application-related project services, application management, application hosting, infrastructure-related project services, infrastructure outsourcing; excluding cloud services.

[7] paid web-based services consisting of IaaS, PaaS, SaaS.

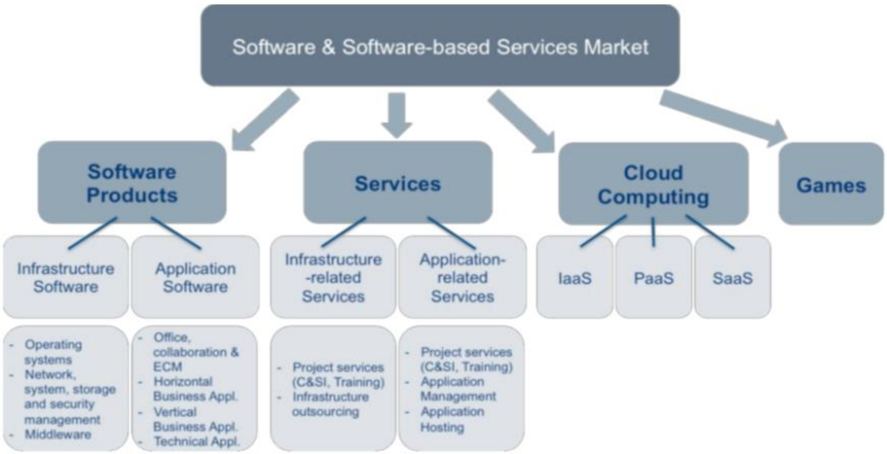

Software & Software-based Services Market
Software Products
Services
Cloud Computing
Games
Infrastructure Software
Application Software
Infrastructure -related Services
Application-related Services
IaaS
PaaS
SaaS
- Operating systems
- Network, system, storage and security management
- Middleware
- Office, collaboration & ECM
- Horizontal Business Appl.
- Vertical Business Appl.
- Technical Appl.
- Project services (C&SI, Training)
- Infrastructure outsourcing
- Project services (C&SI, Training)
- Application Management
- Application Hosting

Figure 3: Software market segmentation[8]

The proxy used (**Software Development - SD**) is not an official Eurostat statistic but represents an indicator built for the purpose of this impact assessment. It aims to provide an estimation of the size of the market and is based on the following NACE 2 activities:[9] [J582] Software publishing, which encompasses; [J5821] Publishing of computer games; [J5829] Other software publishing, and [J6201] Computer programming activities. It is worth noting that the data included in this proxy indicator **excludes** activities linked to consultancy activities ([J6202]) facilities management activities ([J6203]) and other information technology and computer service activities ([J6209]) in line with the scope of the initiative.

The software market in Europe has been growing steadily. Due to constraints of available data, the analysis has been narrowed down by looking at a set of six Member States[10] for which complete data was available. Hence, considering a sub-set of EU Member States, the **SD appears to be growing in all its main indicators** (i.e. production value, turnover and total number of enterprises) over the past five year.[11] While production value and turnover increased of 36 % and 39 % respectively, the number of enterprises in the sector experienced a prominent growth, equal to approximately 44 %.

[8] Pierre Audoin Consultants (PAC) GmbH et al (2017): “The Economic and Social Impact of Software & Services on Competitiveness and Innovation (SMART 2015/0015)”, *A study prepared for the European Commission*, p. 26.

[9] Indicator elaborated by the Second Interim Study Report N° 2019-0024 supporting the impact assessment.

[10] As the database contains several breaks in the time series of the abovementioned indicators, as well as confidential data for some of the Member States (CZ, DE, FR, IT, HU, PL),

[11] Please note that the following filters were applied when selecting the Member States (2019 values): production value ≥ EUR 10 000 million; turnover ≥ EUR 10 000 million and; enterprises ≥ 15 000 in 2019. This allowed the Project Team to focus on the most robust data entry points. Furthermore, Member States that passed the thresholds but had breaks in the time series were also discarded.

Year	2015	2016	2017	2018	2019
Czech Republic	51 669	55 637	61 157	68 229	72 712
Germany	867	11 793	12 705	13 889	14 874
France	20 868	23 131	23 894	24 797	26 816
Italy	19 359	20 157	20 784	20 773	20 384
Hungary	7 094	7 593	8 647	10 320	11 755
Poland	24 141	23 266	21 954	23 525	25 547
TOTAL	**124 000**	**141 577**	**149 141**	**161 533**	**172 088**

Table 14: SD by country – turnover between 2015 and 2019 in EUR million[12]

The Project Team aggregated the statistics provided by Eurostat concerning the structure of the industry by employment class size in order to assess **the presence of SMEs within the software market**. Due to confidentiality, data is not available for all the Member States, therefore the Project Team has selected a sample of countries[13] with full datasets to assess the proportion of SMEs within the software market. Additionally it is worth noting that the data presented in *Table 14* constitutes an **over-estimation of the number of enterprises** as the granularity level available in the dataset does not encompass [J6201] as an indicator but provides the aggregated [J620] which also includes computer consultancy activities ([J6202]), computer facilities management activities ([J6203]) and other information technology and computer service activities ([J6209]).

The results illustrate that the software industry is almost entirely composed of SMEs. In fact, whereas the total number of enterprises for the selected sample amounted to 341 781 in 2019, the number of SME operating in the software market in the same year (*Table 15*) reached 340 918, accounting for 99.7 % of the total. The very large majority (94 %) of SMEs operating in the software market are micro enterprises (less than nine employee). SMEs account for 5 % and 1 % of the market respectively, both relatively more present in the software publishing activity, accounting for a cumulative 11.7 % of total SMEs. However, when looking at the turnover generated by SMEs (*Table 16*) in the software market for sample countries, it accounts for 41 % of the EUR 305 444 billion which shows the important relative weight of big market players that may constitute only 0.3 % of enterprises in the market but generate 59 % of revenue.

SME size (n° of employees)	All	Micro (0-9)	Small (10-49)	Medium (50-249)
[J582] Software publishing	14 379	12693	1 326	360
[J620] Computer programming, consultancy and related activities	326 539	307 667	15 648	3 224
Total	**340 918**	**320 360**	**16 974**	**3 584**
% of SMEs	**100 %**	**94 %**	**5 %**	**1 %**

Table 15: SD in sample EU countries – number of SMEs in 2019[14]

[12] EUROSTAT [SBS_NA_1A_SE_R2]

[13] Please, note that the Project Team applied the following filters when selecting the Member States (2019 values): total number of enterprise for each indicator ≥ 1000. Furthermore, Member States that passed the thresholds but had breaks in the time series were also discarded. The final sample includes France, Germany, Poland, Romania and Spain.

[14] EUROSTAT [SBS_SC_1B_SE_R2]

SME size (n° of employees)	All	Micro (0-9)	Small (10-49)	Medium (50-249)
[J582] Software publishing	11 410.8	1 735.7	3 662.4	6 012.7
[J620] Computer programming, consultancy and related activities	113 242.3	35 740.2	34 009.1	43 493
Total	**124 653.1**	**37 475.9**	**37 671.5**	**49 505.7**
% of SMEs	**100 %**	**30 %**	**30 %**	**40 %**

Table 16: SD in sample EU countries – turnover in million in 2019[15]

According to the literature, it is in principle possible to segment the open source software (OSS) market into commercial open source and non-commercial open source. In opposition to its counterpart, commercial open source is defined as "*open source software projects that are owned by a single firm that derives a direct and significant revenue stream from the software*"[16]. However, as it also emerged during the consultations for this study (interviews, workshop), it is difficult to estimate the commercial value of commercial open source software solely. Therefore, the values provided in this *Box* are to be considered at an over-evaluation of the market as it encompasses non-commercial OSS as well.

It is estimated that companies located in the EU **invested around EUR 1 billion in OSS in 2018**, which resulted in an overall impact on the European economy of between EUR 65 and 95 billion according to a DG CNECT study[17]. In the same study, a survey carried on 900 companies revealed that small and micro enterprises can attribute over half their revenues to OSS, and particularly OSS related services. Respondents (and particularly small and micro respondents) also reported a high percentage of innovation-related expenses, and almost 50 % of their OSS contributions related to internal product development and another 40 % to already existing OSS. When looking at the key actors in the OSS market, EU OSS manufacturers (solo manufacturers, academics, government personnel and employees) contribute significantly to the global OSS ecosystem. However, it is employees of small and very small businesses that are most likely to contribute OSS code ("commits") in the EU, whereas in other markets, such as the US, commits are mostly made by large manufacturers of products with digital elements. European contributors are estimated to be at least 260 000, representing 8 % of the almost 3.1 million EU employees in the computer programming sector in 2018. 50 % of contributors are already within the ICT industry (8 % of all employees participated in OSS development EU-wide).

	2019	**2020**	**Growth**
Open Source Software & IT Services market			
Production Value (in million EUR)	5 233	5 684	*8.6 %*
Share in software market	10.30 %	10.70 %	-
Employment (FTEs)	52 400	56 700	*8.2 %*
Zoom into Open Source Software production values (in EUR million)			

[15] EUROSTAT [SBS_SC_1B_SE_R2]

[16] Riehle, D. (2009). The Commercial Open Source Business Model. In: Nelson, M.L., Shaw, M.J., Strader, T.J. (eds) Value Creation in E-Business Management. AMCIS 2009. Lecture Notes in Business Information Processing, vol 36. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-03132-8_2

[17] European Commission, Directorate-General for Communications Networks, Content and Technology, Blind, K., Pätsch, S., Muto, S., et al. (2021) The impact of open source software and hardware on technological independence, competitiveness and innovation in the EU economy: final study report. Publications Office. https://data.europa.eu/doi/10.2759/430161. The analysis estimates a cost-benefit ratio of above 1:4 and predicts that an increase of 10% of OSS contributions would annually generate an additional 0.4% to 0.6% GDP as well as more than 600 additional ICT start-ups in the EU, p. 14.

Open Source Software	365	403	*10.4 %*
Infrastructure Software & Platforms	199	229	*15.1 %*
Application Software Products	129	138	*7.0 %*
SaaS	27	36	*33.3 %*

Table 17: A closer look at the OSS market in France[18]

As a representation of the growth of the OSS market in the Member States, *Table 17* above includes key metrics to assess the size and growth of such a market in a sample country (France). The data shows a rapid growth of OSS in France, a growth that is assessed as slightly higher than the overall software market, as the market share of OSS & IT services is estimated to have grown by 0.4 percentage points between 2019 and 2020. Similarly, when looking more closely to software available as OSS, a vast majority both in terms of production and growth is carried by infrastructure software and platforms, followed by application software products. Open Source Software as a Service (SaaS) remains a minimal part of the OSS available on the market (8.9 % in 2020) but is the fastest growing market segment (33.3 % from 2019 to 2020).

Box 4: The open source software (OSS) market – outlook

Trends in the EU software market

Along with the rest of the ICT sector, the economic outlook for the software market is positive, having continued to grow throughout the pandemic crisis. Indeed, spending in the software market has seen a year to year growth rate of about 5 % in 2020, a number expected to remain constant in 2021.

As highlighted by the European Parliament in the Global Trends to 2035,[19] the software market will continue evolving with a high reliance on **automation** and **artificial intelligence** in many industries. According to the International Data Corporation (IDC), AI spending is expected to rise by 33 % between 2020 and 2023.

The software market is also impacted by technological advancements such as the surge of **big data** analytics and faster data processing enables business to drive down costs and better define their business strategies by leveraging business intelligence tools and software enabling to make informed decisions based on data (e.g. market trends and consumer buying patterns). The global business intelligence software market size was valued at EUR 23.87 billion in 2018 and is expected to witness a CAGR of 10.1 % from 2019 to 2025.[20]

Trade in EU software market

According to the CN classification, the software is classified according to:[21] *The media on which it's been recorded and the nature of the software. Media include CD, DVD, Laserdisc, Minidisc and other laser-read disks. Even though there are differences in the manufacturing and recording - or writing - processes, these are all designed to be read by some kind of laser system once recorded, floppy disks, magnetic tapes, magnetic stripe cards, memory cards, cartridges for video games consoles. For the purposes of Tariff classification, software categories include: programs and data, sound recordings, computer games, films, pictures and image files, games for video games consoles.*

[18] https://cnll.fr/media/2019_CNLL-Syntec-Systematic-Open-Source-Study.pdf

[19] https://www.oxan.com/media/1969/global-trends-to-2035-geopolitics-and-power.pdf.

[20] Business Intelligence Software Market Size, Share & Trends Analysis Report […], 2019 – 2025. Retrieved from https://www.grandviewresearch.com.

[21] https://trade.ec.europa.eu/access-to-markets/en/content/classifying-computers-and-software

As explained at the beginning of this section, this classification is fully based on products and cannot be directly compared to classifications based on economic activity (e.g. NACE). The latter is at the same time more aggregated, but also better able to reflect the intangible nature of the activities underlying the production of software.

We have then selected the code **8523** (Discs, tapes, solid-state non-volatile storage devices, 'smart cards' and other media for the recording of sound or of other phenomena, whether or not recorded, including matrices and masters for the production of discs) that covers all those software categories.

In percentage terms, compared to hardware, the software share of **extra-EU imports** is lower, and it is separated from that of **intra-EU27 imports** by 18 percentage points (see *Figure 4*). When looking at the figure by country, Ireland (EUR 629 329 645) and the Netherlands (EUR 974 898 158) have higher values of imports from extra-EU27 than intra-EU27. Also, Germany (highest value of extra-EU imports in absolute terms, namely EUR 1 028 886 828), Poland (EUR 584 605 358) and France (EUR 453 722 408) have high values of extra-EU imports, however, for those countries values are lower than intra-EU27 imports.

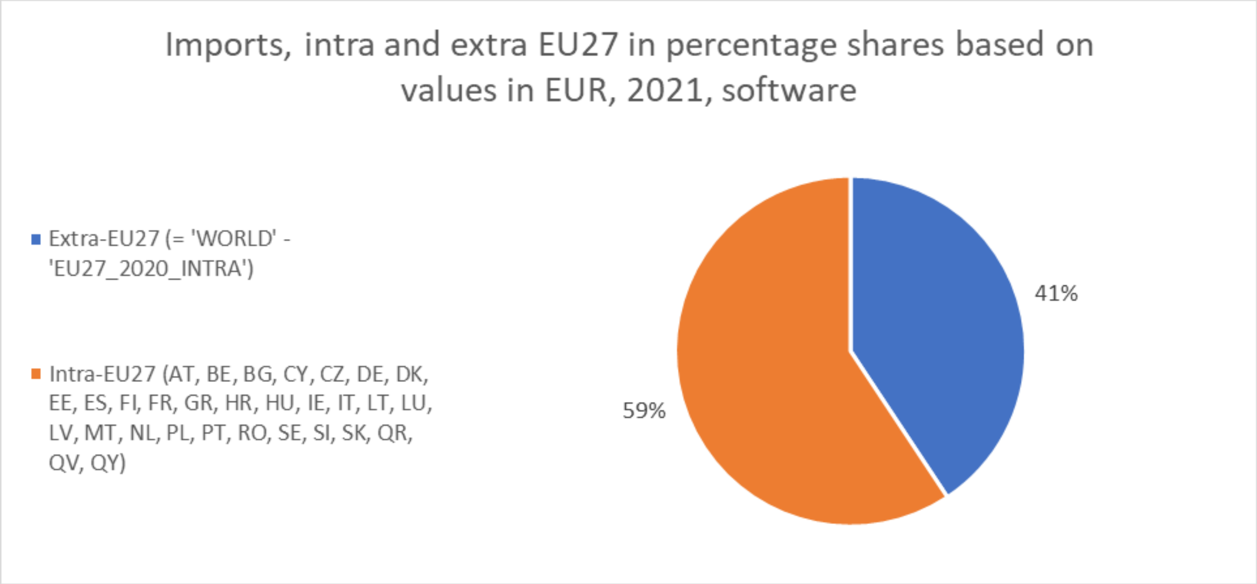


Figure 4: Imports, intra and extra EU27, in percentage shares based on values in EUR, 2021, software[22]

[22] Authors' calculation based on COMEXT – Eurostat

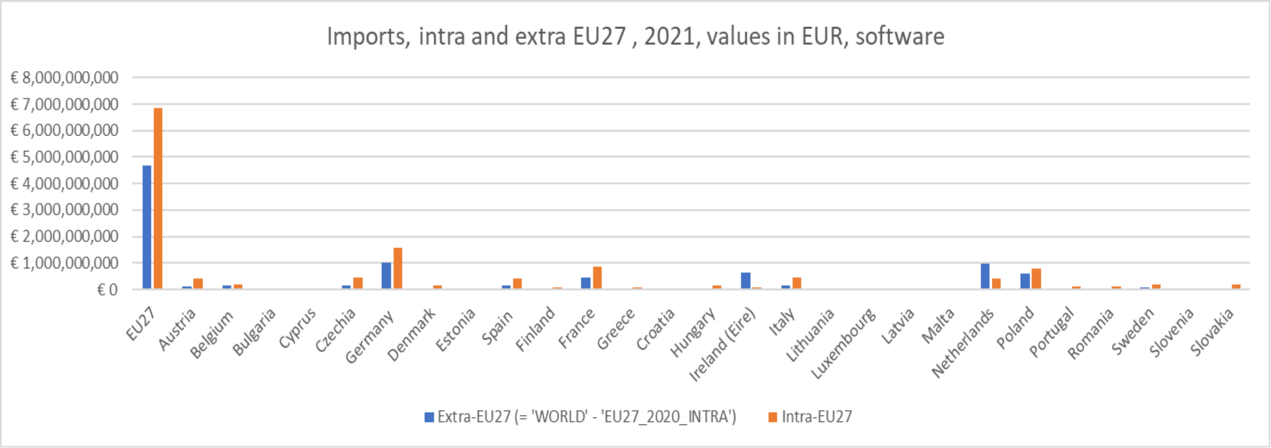


Figure 5: Imports, intra and extra EU27, values in EUR, 2021, software[23]

[23] Authors’ calculation based on COMEXT - Eurostat

The EU hardware market

Methodology

Proxies were used to assess the dimension of the hardware market. The data on ICT-SC could be considered as under-representative of the overall market for hardware products as it does not account for manufactured products produced in other sectors (e.g. smart toys), which can be digitally connected. This can lead to an underestimation of impacts. Therefore, the analysis of impacts also considers the extended classification (ICT-EXC-ADJ), representing a sub-set of 2-digit NACE 2 activities of the manufacturing sector combined with a weighting coefficient allowing for a more accurate assessment of the hardware market

The proxies used to provide an estimation of the size of the market are:

1. ICT manufacturing sector – standard classification (ICT-SC), representing a sub-set of 3-digit NACE 2 activities of the manufacturing sector. The ICT-SC is used by Eurostat as standard classification for economic activity. The NACE 2 activities included in the ICT-SC are:
    - [C261] Manufacture of electronic components and boards;
    - [C262] Manufacture of computers and peripheral equipment;
    - [C263] Manufacture of communication equipment;
    - [C264] Manufacture of consumer electronics; and
    - [C268] Manufacture of magnetic and optical media.

    It is worth noting that the data on ICT-SC could be considered as under-representative of the overall market for hardware products as intended by the scope of this study, as it does not account for products manufactured in other sectors (e.g.; smart toys in C324) which can be digitally connected. Nevertheless, at present, ICT-SC appears to be the most appropriate proxy to assess the hardware market as similar classifications are also used in relevant publications.[24]

2. ICT manufacturing sector – extended classification (ICT-EXC), representing a sub-set of 2-digit NACE 2 activities of the manufacturing sector. The ICT-EXC is not an official Eurostat statistic but represents an indicator built by the Project Team for the purpose of this study. The NACE 2 activities included in the ICT-EXC are:
    - [C26] Manufacture of computer, electronic and optical products;
    - [C27] Manufacture of electrical equipment;
    - [C28] Manufacture of machinery and equipment n.e.c.;
    - [C30] Manufacture of other transport equipment;
    - [C32] Other manufacturing; and
    - [C33] Repair and installation of machinery and equipment.

    The ICT-EXC can be considered the upper limit for the assessment of the size of the hardware market. It is worth noting that the ICT-EXC assumes that all the products manufactured in these sectors are digital or feature a digital component. This is indeed a relevant limitation of this approach as it overestimates the size of the hardware market. For this reason, the Project Team applied a weighting coefficient allowing for a more accurate assessment of the hardware market. Particularly, this study applies the percentage of enterprises integrating digital

[24] See footnote 140.

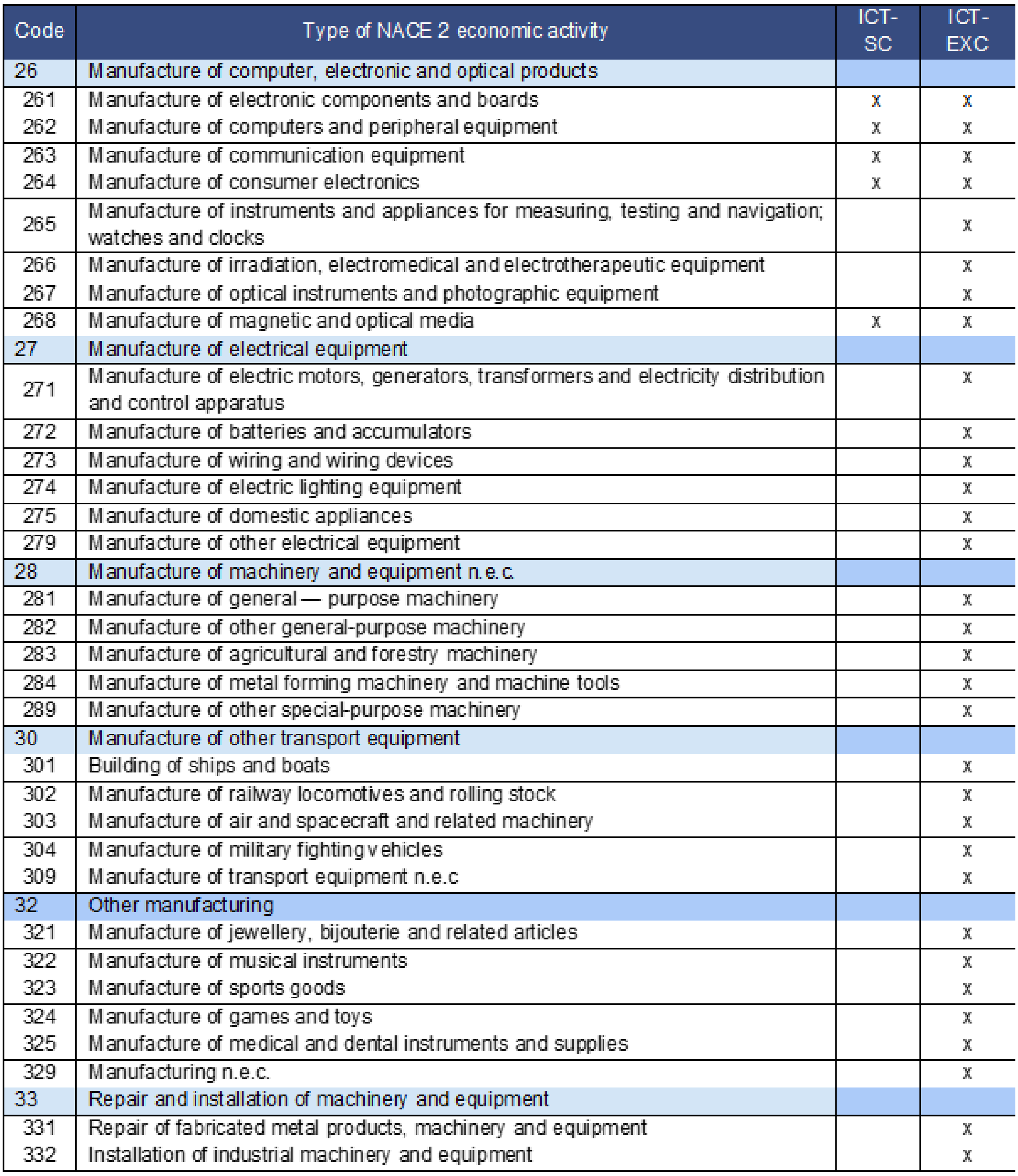
processes to the selected ICT-EXC indicators to all the NACE 2 2-digit activities selected by the Project Team (see above), with the exception of C26 which is considered in its entirety.[25]

The calculation of the different indicators will be performed by using the formula below, providing ICT-EXT adjusted (ADJ) results. The Project Team recognises that the percentage of enterprises integrating digital processes (K in the formula below) represents a sub-optimal coefficient as it does not refer to the production of products with digital elements within the sectors, but to measures of digital intensity within the production process. This happens because the NACE classification is 'economic activity-based', and not 'product-based' classification. As the coefficient differs for each NACE 2 activity, *Table 19* presents the coefficient applied to each activity for the purpose of this study. Hence, the parameters of the NACE 2 activities are adjusted by multiplying the total value with the coefficients of *Table 19*.

$$\textit{ICT-EXT-ADJ indicator} = C26 * K^{C26} + C27 * K^{C27} + C28 * K^{C28} + C30 * K^{C30} + C32 * K^{C32} + C32 * K^{C32}$$

Table 18 shows the NACE 2 activities included by the Project Team in the different proxies used to assess the hardware market.

[25] 'C26 Manufacture of computer, electronic and optical products' represents the core ICT sector as defined by Eurostat. Hence, as for the calculation of the market size for ICT-SC, the Project Team will consider it in its entirety so to be able to apply the coefficient at the same NACE 2 (2-digit) level. The coefficients for the percentage of enterprises integrating digital processes are not available at NACE 2 3-digit level.



Code	Type of NACE 2 economic activity	ICT-SC	ICT-EXC
26	Manufacture of computer, electronic and optical products		
261	Manufacture of electronic components and boards	x	x
262	Manufacture of computers and peripheral equipment	x	x
263	Manufacture of communication equipment	x	x
264	Manufacture of consumer electronics	x	x
265	Manufacture of instruments and appliances for measuring, testing and navigation; watches and clocks		x
266	Manufacture of irradiation, electromedical and electrotherapeutic equipment		x
267	Manufacture of optical instruments and photographic equipment		x
268	Manufacture of magnetic and optical media	x	x
27	Manufacture of electrical equipment		
271	Manufacture of electric motors, generators, transformers and electricity distribution and control apparatus		x
272	Manufacture of batteries and accumulators		x
273	Manufacture of wiring and wiring devices		x
274	Manufacture of electric lighting equipment		x
275	Manufacture of domestic appliances		x
279	Manufacture of other electrical equipment		x
28	Manufacture of machinery and equipment n. e. c.		
281	Manufacture of general — purpose machinery		x
282	Manufacture of other general-purpose machinery		x
283	Manufacture of agricultural and forestry machinery		x
284	Manufacture of metal forming machinery and machine tools		x
289	Manufacture of other special-purpose machinery		x
30	Manufacture of other transport equipment		
301	Building of ships and boats		x
302	Manufacture of railway locomotives and rolling stock		x
303	Manufacture of air and spacecraft and related machinery		x
304	Manufacture of military fighting vehicles		x
309	Manufacture of transport equipment n.e.c		x
32	Other manufacturing		
321	Manufacture of jewellery, bijouterie and related articles		x
322	Manufacture of musical instruments		x
323	Manufacture of sports goods		x
324	Manufacture of games and toys		x
325	Manufacture of medical and dental instruments and supplies		x
329	Manufacturing n.e.c.		x
33	Repair and installation of machinery and equipment		
331	Repair of fabricated metal products, machinery and equipment		x
332	Installation of industrial machinery and equipment		x

Table 18: Proxies and NACE 2 activities[26]

[26] European Commission Digital Economy and Society Index (DESI)

Code	Type of NACE 2 economic activity	Share enterprises digital processes (2019)
26	Manufacture of computer, electronic and optical products	1[1]
27	Manufacture of electrical equipment	63%
28	Manufacture of machinery and equipment n.e.c.	60%
30	Manufacture of other transport equipment	60%
32	Other manufacturing	40%
33	Repair and installation of machinery and equipment	40%

Table 19: Share of enterprises implementing digital processes by NACE2 activity – ICT-EXT-ADJ[27]

ICT manufacturing sector – standard classification

In 2019, the **production value** of the EU-27 ICT-SC amounted to EUR 222 billion. During the same year, the sector recorded a **turnover** of EUR 285 billion[28] with a total **number of enterprises** of 22 773.[29]

As the database contains several breaks in the time series of the abovementioned indicators, the Project Team narrowed down the analysis by looking at a set of six Member States for which complete data was available. Hence, considering a sub-set of EU Member States, the ICT-SC appears to be growing in all its main indicators (i.e.; production value, turnover and total number of enterprises) over the past five year.[30] *Table 20*, *Table 21* and *Table 22* illustrate the upward trend over time of these indicators in the selected countries. Particularly, while production value and turnover increased of 21 % and 23 % respectively between 2015 and 2019, the number of enterprises in the sector experienced a less prominent growth, equal to approximately 13 % over the same reference period.

Year	2015	2016	2017	2018	2019
Czech Republic	8 071.5	8 193.4	8 351.8	9 676.7	9 427.7
Germany	33 698.4	33 270.9	33 069.9	34 186.6	34 841.1
France	16 067.5	16 487.5	14 895.8	22 653.9	26 720.1
Italy	10 382.7	10 695.5	10 927.5	11 720.1	12 087.0
Hungary	9 540.3	9 908.3	10 596.7	10 174.7	12 320.2
Poland	7 608.5	7 101.0	7 805.9	8 110.9	8 042.4
TOTAL	**85 368.9**	**85 656.6**	**85 647.6**	**96 522.9**	**103 438.5**

Table 20: ICT-SC by country - production value between 2015 and 2019 in EUR million[31]

[27] European Commission Digital Economy and Society Index (DESI)

[28] This data appears to be consistent with other estimations. For instance, Research and Markets assess the IT Hardware Market in Europe at USD 228.9 billion in 2020. The IT hardware market includes all physical components integral to computing such as computing, networking, security and server hardware. More info available at: https://www.researchandmarkets.com/reports/5350389/it-hardware-in-europe-market-summary

[29] EUROSTAT. Annual enterprise statistics for special aggregates of activities (NACE Rev. 2). [SBS_NA_SCA_R2]

[30] Please note that the Project Team applied the following filters when selecting the Member States (2019 values): production value ≥ EUR 8 000 million; turnover ≥ EUR 8 000 million and; enterprises ≥ 1 000 in 2019. This allowed the Project Team to focus on the most robust data entry points. Furthermore, Member States that passed the thresholds but had breaks in the time series were also discarded.

[31] EUROSTAT [SBS_NA_SCA_R2]

Year	2015	2016	2017	2018	2019
Czech Republic	8 315.1	8 391.6	8 860.9	10 190.8	9 956.7
Germany	37 761.7	37 459.8	37 671.6	43 272.4	41 746.9
France	16 792.0	17 439.5	15 387.2	23 585.0	27 364.9
Italy	10 495.0	10 770.6	11 093.8	11 293.2	11 678.3
Hungary	10 939.4	11 453.1	12 113.0	11 491.5	14 143.9
Poland	8 127.0	7 675.4	8 207.4	8 981.8	8 895.9
TOTAL	**92 430.2**	**93 190.0**	**93 333.9**	**108 814.7**	**113 786.6**

Table 21: ICT-SC by country - turnover between 2015 and 2019 in EUR million[32]

Year	2015	2016	2017	2018	2019
Czech Republic	2 348	2 326	2 303	2 238	2 260
Germany	3 762	3 684	3 644	4 275	4 423
France	1 693	1 632	1 381	1 417	1 416
Italy	3 370	3 327	3 265	3 204	3 303
Netherlands	919	909	926	1 015	1 050
Poland	1 738	1 896	2 019	2 428	2 448
Slovakia	621	920	974	1 388	1 414
TOTAL	**14 451**	**14 694**	**14 512**	**15 965**	**16 314**

Table 22: ICT-SC by country - number of enterprises between 2015 and 2019[33]

When referring to turnover, it is difficult to assess the share of the **revenues related to B2C and B2B**. Nevertheless, by looking at the German hardware market, it is possible to highlight that revenues from hardware sales are equally split between B2B (48.1 %) and B2C (51.9 %) sectors in 2018. The reason behind this split is the strong consumer business stream connected to the sale of smartphones, laptops and general consumer. This represents an important distinction with the software and services market where the B2B component is predominant, accounting for more than two-thirds of the overall sales.[34]

The device market – outlook[35]

The device market is a segment of the IT hardware market, including PCs and phones sub-segments. While the PCs' segment encompasses physical units of computing systems (e.g.; tablets), the phones' segment includes mobiles and fixed lines used both by businesses and consumers. The global revenues of the device market amounted to **EUR 766 billion in 2021**, with Europe accounting for 24 % of the total (**EUR 184 billion**).[36]

The phones' segment represents the most relevant part of the device market with a total revenue of EUR 511 million in 2021 and expected to reach EUR 586 billion by 2026 (CAGR equal to 2.8 %). The European phones' market accounts for 23 % of the total in 2021 (**EUR 117 billion)**, with Germany and France being the two main markets (EUR 17 and 12 billion respectively)[37].

The PC' segment reached global revenues for EUR 255 billion in 2021, with Europe accounting for 26 % of the total (**EUR 66 billion**). The segment is expected to have a

[32] EUROSTAT [SBS_NA_SCA_R2]
[33] EUROSTAT [SBS_NA_SCA_R2]
[34] Deloitte (2019). The German Technology Sector. From Hardware to Software & Services. p. 12
[35] Statista (2021). Devices Report 2021 -Statista Technology Market Outlook. December 2021.
[36] Currency exchange rate EUR/USD on 16/05/2022.
[37] Currency exchange rate on 06/05/2022

slower growth than the phones' segment as the CAGR is expected to be 0.9 % until 2026.

The Project Team aggregated the statistics provided by Eurostat concerning the structure of the industry by employment class size to assess **the presence of SMEs within the hardware market**. The results illustrate that the European ICT-SC manufacturing industry is almost entirely composed of SMEs. In fact, whereas the total number of enterprises amounted to 22 773 in 2019, the number of SME operating in the hardware market in the same year reached 22 119, accounting for 97.13 % of the total. The large majority (82 %) of SMEs operating in the hardware market are micro enterprises (less than nine employee). SMEs account for 14 % and 4 % of the market respectively, the latter being relatively more present in the manufacturing of electronic components and boards, amounting to 5.7 % of the total SMEs. However, when looking at the turnover generated by SMEs in the hardware market, it accounts for 21.9 % of the global turnover which shows the very important weight of larger companies that may constitute only 2.87 % of enterprises in the market but generate 78.1 % of revenue.

SME size (n° of employees)	All	Micro (0-9)	Small (10-49)	Medium (50-249)
Manufacture of electronic components and boards (C261)	9 669	7 333	1 781	555
Manufacture of computers and peripheral equipment (C262)	5 347	4 745	462	140
Manufacture of communication equipment (C263)	4 629	3 815	591	223
Manufacture of consumer electronics (C264)	2 462	2 201	198	63
Manufacture of magnetic and optical media (C268)	12	*NA*	12	*NA*
Total	**22 119**	**18 094**	**3 044**	**981**
% SMEs	**100 %**	**82 %**	**14 %**	**4 %**

Table 23: ICT-SC in EU-27 - number of SMEs in 2019 by size[38]

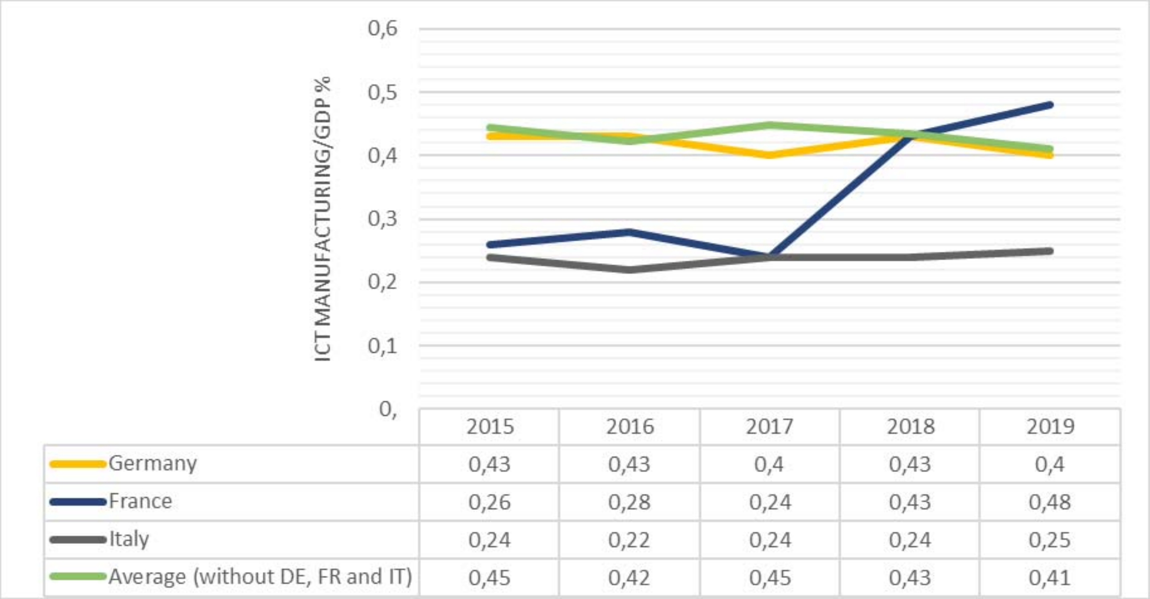
SME size (n° of employees)	All	Micro (0-9)	Small (10-49)	Medium (50-249)
Manufacture of electronic components and boards (C261)	19 071.7	2 346.0	5 357.8	11 367.9
Manufacture of computers and peripheral equipment (C262)	3 263.7	1 240.4	2 023.3	*NA*
Manufacture of communication equipment (C263)	9 234.0	1 784.4	1 942.1	5 507.5
Manufacture of consumer electronics (C264)	2 595.8	325.4	725.2	1 545.2
Manufacture of magnetic and optical media (C268)	86.3	33.4	52.9	*NA*
Total	**34 251.5**	**5 729.6**	**10 101.3**	**18 420.6**
% SMEs	**100 %**	**82 %**	**14 %**	**4 %**

Table 24: ICT-SC in EU-27 – turnover in EUR million in 2019 by size[39]

The **weight of the ICT manufacturing** on the overall European economy was stable over the past five years and still appears to be limited, amounting to 0.41 % in 2019.[40] *Figure 6* presents the evolution of the relative weight of the ICT-SC on the GDP of the main

[38] EUROSTAT [SBS_SC_IND_R2]
[39] EUROSTAT [SBS_SC_IND_R2]
[40] EUROSTAT. Percentage of the ICT sector on GDP. [TIN00074]

European economies (i.e.: Germany, France and Italy) between 2015 and 2019. While France experienced a substantial increase in the relative weight of the sector, Germany and Italy ICT-SC manufacturing did not change over the period under analysis. Furthermore, the graph outlines the average of the same indicator for a larger set of EU Member States.[41]



	2015	2016	2017	2018	2019
Germany	0,43	0,43	0,4	0,43	0,4
France	0,26	0,28	0,24	0,43	0,48
Italy	0,24	0,22	0,24	0,24	0,25
Average (without DE, FR and IT)	0,45	0,42	0,45	0,43	0,41

Figure 6: Percentage of the ICT-SC on GDP - Value added at factor cost in the ICT-SC sector[42]

In 2018, the **value added** of the ICT sector in the EU-27 amounted to EUR 590 billion. Nevertheless, more than 90 % of the value-added concerns ICT services, with ICT-SC accounting for a marginal part over the total. Moreover, it is important to point out that, while the ICT service sector experienced an upward trend in the value-added between 2006 and 2018, the ICT-SC witnessed a slight decline in the same period.[43] *Figure* 7 presents the value-added trend over between 2006 and 2020 (please note that 2019 and 2020 represent nowcasted data.

[41] Namely the average of Belgium; Bulgaria; Czech Republic; Estonia; Greece; Croatia; Lithuania; Hungary; Austria; Poland; Romania; Slovenia; Slovakia.

[42] EUROSTAT [TIN00074]

[43] European Commission (2021). Digital Economy and Society Index (DESI) 2021, p. 77.

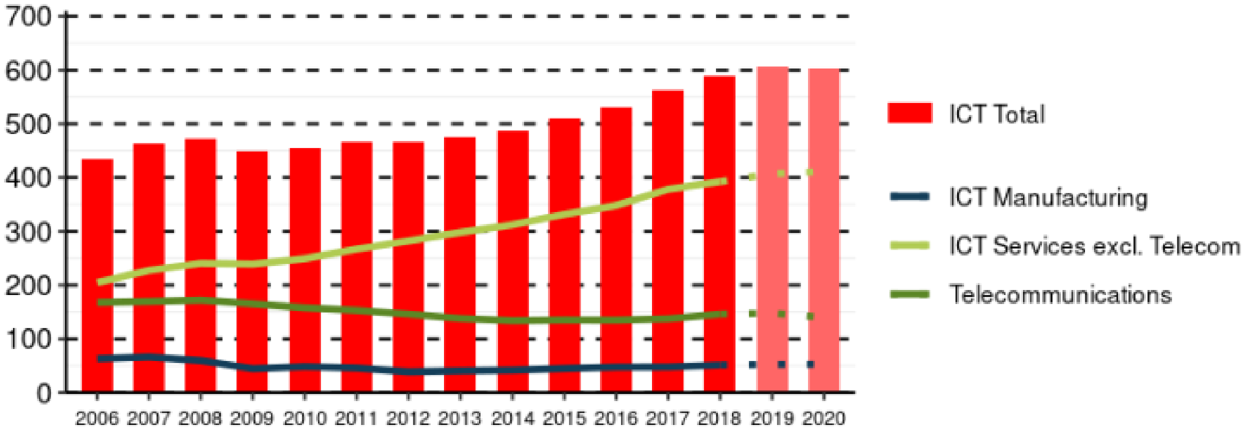


Figure 7: ICT-SC value-added between 2006 and 2020 - EUR billion[44]

ICT manufacturing sector – extended classification

When considering the **ICT-EXT-ADJ**, the production value of the EU-27 amounted to EUR 1 081 billion, the turnover to EUR 1 220 billion and the total number of enterprises of 249 513 in 2019. *Figure 8* provides a breakdown by NACE 2 activities of the estimated market size for hardware in 2019. The manufacture of machinery equipment and n.e.c. represents the main one for production value and turnover. On the contrary, repair and installation of machinery equipment is the NACE 2 activity with the highest number of enterprises.

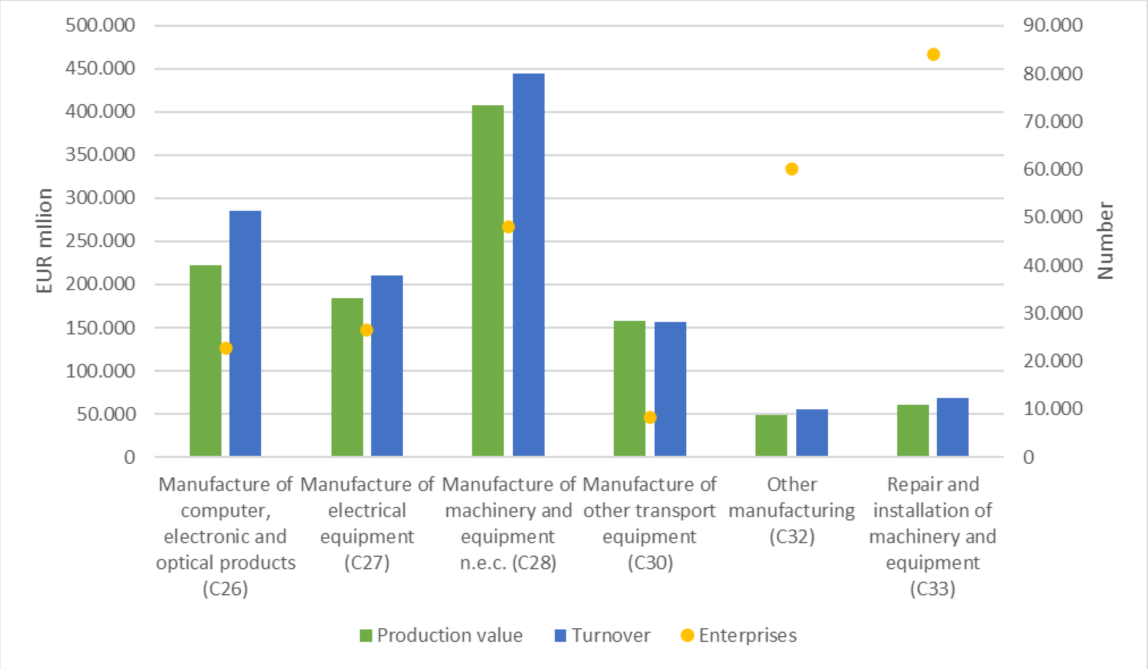


Figure 8: Breakdown of indicators by NACE2 activities (ICT-EXC-ADJ) – EU27, 2019[45]

Semiconductors (also known as chips) are substances that have specific electrical properties allowing them to ensure the conductivity between conductors and insulators, making them a founding component for computers and other electronic devices.

[44] European Commission (2021). Digital Economy and Society Index (DESI) 2021, p. 77.

[45] Eurostat data.

Semiconductors are essential to many commonly used hardware products such as smartphones, tablets or PCs. The European Semiconductor Industry Association (ESIA) reported that **yearly semiconductor sales in the European market reached EUR 44.57 billion in 2021, a 27.3 % increase versus 2020**. As global reliance on electronics continues to grow, the potential market for semiconductor manufacturers and retailers will continue to increase as well. 2022 is expected to reach two-digit growth compared to the previous year, with revenue from sales expected to amount to EUR 49 billion.[46][47]

Globally, semiconductor sales amounted to EUR 518.81 billion in 2021, a 26.2 % increase from 2020. Therefore, the European market for semiconductors represented, in 2021, 8.6 % of global sales, a slight increase from the 8.5 % of 2020.[48] However, sales from 2019 to 2020 have seen a slower increase globally and even decreased in Europe as shown below. The lag encountered in the European semiconductor market has been increasingly catching up since 2020 with increasing forecasted sales. This growth in the European market is expected to exceed the global figure with the market share dedicated to European enterprises increasing from year to year.

Semiconductor global and European market outlook[49]

	2019	2020	2021	2022*
Global semiconductor sales (in EUR billion)	384.1	411.1	518.8	560.0
Growth	-	*7 %*	*26 %*	*8 %*
European semiconductor sales (in EUR billion)	37.2	35.0	44.6	49.4
Growth	-	*-6 %*	*27 %*	*11 %*
European market share	9.7 %	8.5 %	8.6 %	8.8 %

**Values for 2022 are forecast estimates*

The sharp increase in demand, fuelled by the effects of the COVID-19 pandemic, over the past three years has lead to a shortage in the supply of semiconductors heavily impacting a variety of industries such as automotive, health, defence or security. This global semiconductor shortage has exposed European dependency on supply from a limited number of companies and geographies, and its vulnerability to third country export restrictions and other disruptions in the present geopolitical context. Therefore, in line with the Commission's objective of creating a state-of-the-art European chip ecosystem[50], the Commission released a proposal for a Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act)[51]. The EU Chips Act proposes to develop a thriving semiconductor ecosystem and resilient supply chain, while setting measures to prepare, anticipate and respond to future supply chain disruptions. To this end, if approved, the European Chips Act will have more than EUR 43 billion in place to support the development of European semiconductor supply chains.

Box 5: The semiconductor market – outlook

Markets trends

[46] Currency exchange rate EUR/USD on 16/05/2022.

[47] Statistics available here.

[48] https://www.eusemiconductors.eu/sites/default/files/ESIA_WSTS_PR_2112.pdf

[49] https://www.statista.com/topics/1182/semiconductors/

[50] State of the Union address 2021. https://ec.europa.eu/info/sites/default/files/soteu_2021_address_en_0.pdf

[51] Chips Act Proposal COM(2022) 46 final..

Despite the impacts of the COVID-19 pandemic, the **IT budget of European companies appears to be growing in 2022,** as outlined by a survey.[52] Particularly, more than half of the sample declared that the IT budget will increase during the year. This trend appears to be more prominent when considering big (more than 500 employees) corporations where two-thirds of the sample signalled its intention to increase the budget. Within the IT budget, hardware represents the **largest share of the spending** (30 % in 2022), especially for SMEs.

While not specific only the hardware market, an important trend concerning hardware is the **continuous growth of the IoT sector**. Particularly, IoT spending will grow at CAGR of 12.32 % from EUR 131 billion in 2019 to EUR 230 billion in 2024.[53] By looking at the application level, the revenue in the European IoT market, including smart home technologies and smart finance technologies but excluding other IoT use cases, is projected to reach EUR 5.04 billion in 2022 and is foreseen to witness an CAGR equal to 10.5 % between 2022 and 2027, resulting in a market volume of EUR 8.14 billion by 2027.[54] Other IoT use cases (e.g.; autonomous cars, industrial IoT) represent more relevant market sub-segments, accounting for EUR 20.17 billion in 2020.[55] It is worth noting that this figure includes software and thus, it is an over-representation of the market segment.

An important trend concerning hardware is the **continuous growth of the IoT market**. The IoT market refers to all internet-enabled objects and devices that collect and exchange data. IoT products include wearables (e.g. smartwatch), smart home devices, security systems, thermostats, intelligent transportation, smart grids, and many more. They may also be referred to as connected things or smart devices. It is possible to define the European IoT market by considering it in three main ways:[56]

- **Infrastructure** – the market is segmented into platform, mobile networks and access technologies, cloud solutions/storage and processing, analytics and security;
- **Vertical** – the market is segmented into healthcare, energy, public & services, transportation, retail, individuals, and others (e.g.; manufacturing); and
- **Application –** the market is segmented into smart home, smart wearable, smart cities, smart grid, IoT industrial internet, IoT connected cars, IoT connected healthcare, and others (e.g..; toys and drones).

The IoT market represents an important part of the hardware market. The European IoT spending is expected to grow rapidly in the upcoming years. Particularly, IoT spending are forecasted to grow at CAGR of 12.32 % from EUR 131 billion in 2019 to EUR 230 billion in 2024.[57] The IoT spending encompasses not only hardware but also connectivity, services and software spending. However, hardware remains the most relevant component of the spending, accounting for a third of the total.
Looking at revenue from the IoT market in Europe, it increased in 2021 to around EUR 4.47 billion, up from around EUR 3.07 billion in 2020.[58] By focusing at the application level (e.g. smart home, smart wearable, smart cities, smart grid, IoT industrial internet),

[52] https://swzd.com/resources/state-of-it/#soit-2022
[53] Commission (2021). Advanced Technologies for Industry – AT WATCH. Technology Focus on the Internet of Things. March 2021.
[54] https://www.statista.com/outlook/tmo/internet-of-things/europe
[55] https://www.marketwatch.com/press-release/europe-industrial-iot-market-2021-to-2030-new-study-industry-scope-and-growth-strategies-progressing-at-a-cagr-of-107-during-the-forecast-period-2022-02-22
[56] https://www.researchandmarkets.com/reports/5013423/european-iot-market-2019-2025
[57] European Commission (2021). Advanced Technologies for Industry – AT WATCH. Technology Focus on the Internet of Things. March 2021.
[58] Currency exchange rate EUR/USD on 27/05/2022.

the revenue in the European IoT market, including smart home technologies and smart finance technologies but excluding other IoT use cases, is projected to reach EUR 5.04 billion in 2022 and is foreseen to witness an annual growth rate (CAGR) equal to 10.5 % between 2022 and 2027, resulting in a market volume of EUR 8.14 billion by 2027.[59] Other IoT use cases (e.g.; autonomous cars, industrial IoT) represent more relevant market sub-segments, accounting for EUR 20.17 billion in 2020.[60] It is worth noting that this figure includes software.

Box 6: The IoT market – outlook

The hardware market is also experiencing **new technological trends such as tinyML and low power wide area network (LPWAN).** These technological developments seek to address the challenges of high operating costs of machine learning and IoT technologies, while increasing the power efficiency of traditional hardware. TinyML is a machine learning technology allowing users to run on-device, local, sensor data analytics at low-latency, low power and low bandwidth. Consequently, TinyML devices can operate ML applications while being unplugged on batteries for long periods of time (i..; in some cases years). This hardware technology is currently being used in several fields of application such as industrial productive maintenance, agriculture, healthcare and maritime conservation. LPWAN represents a set of low-power, long range area network technologies for small sensor-based data. As LPWAN operate with very little data rates and low power, the hardware underlying these systems can be developed at a very low cost. In 2020, the LPWAN market amounted to more than EUR 2.4 billion (with the European market surpassing EUR 575 million) and is expected to grow at a CAGR of over 60% between 2021 and 2027. Particularly, the German market is forecasted at more than EUR 3 billion by 2027 as both the government and the industry renewed their efforts to replace traditional approaches with LPWAN implementations.

Trade in the EU hardware sector

When selecting relevant codes from the CN classification to reflect the size of imports and exports of hardware, the methodological choice has been made to select all codes at 4-digit level (e.g. Electrical machines and apparatus, having individual functions) that classify **computers and computer parts**, as these codes cover for most of the machinery and other types of products such as basic units and components that play a digital function within a product. We are aware that, given the wide range of products and 'smart' products that the legislation could cover, some codes might be left out by this selection. While making the selection of these codes, the 8-digit level was studied too, in order to assess the relevance of including the specific codes or making a choice to exclude them (e.g. in case they refer to purely passive components, for example, code 8524 *Flat panel display modules, whether or not incorporating touch sensitive screens* are excluded because they do not incorporate drivers or circuits). The main codes selected are:

- **8443** Printing machinery used for printing by means of plates, cylinders and other printing components of heading 8442; other printers, copying machines and facsimile machines, whether or not combined; parts and accessories (**note:** codes 8443 31, 8443 32 are particularly relevant for products with digital elements with smart functions as they refer to *Machines which perform two or more of the functions of printing, copying or facsimile transmission, capable of connecting to an automatic data processing machine or to a*

[59] https://www.statista.com/outlook/tmo/internet-of-things/europe
[60] https://www.marketwatch.com/press-release/europe-industrial-iot-market-2021-to-2030-new-study-industry-scope-and-growth-strategies-progressing-at-a-cagr-of-107-during-the-forecast-period-2022-02-22

network and – *Other, capable of connecting to an automatic data-processing machine or to a network*).

- **8471** Automatic data-processing machines and units thereof; magnetic or optical readers, machines for transcribing data onto data media in coded form and machines for processing such data (**note:** all sub-codes are highly relevant for products with digital elements).
- **8473** Parts and accessories (other than covers, carrying cases, and the like) suitable for use solely or principally with machines of headings 8470 Calculating machines and pocket-size data recording, reproducing, and displaying machines with calculating functions, and to 8472 Other office machines (for example, hectograph or stencil duplicating machines, addressing machines, automatic banknote dispensers, coin-sorting machines) **(note**: this code represents all computer parts. There is a code 8542, that refers to electric circuits however, Eurostat does not include this code within the classifications linked to computers, computer parts, and software).
- **8504** Electrical transformers, static converters (for example, rectifiers) and inductors (code 8504 40 30 is – Of a kind used with telecommunication apparatus, automatic data-processing machines and units).
- **8514** Industrial or laboratory electric furnaces and ovens (including those functioning by induction or dielectric loss); other industrial or laboratory equipment for the heat treatment of materials by induction or dielectric loss.
- **8517** Telephone sets, including smartphones and other telephones for cellular networks or for other wireless networks; other apparatus for the transmission or reception of voice, images or other data, including apparatus for communication in a wired or wireless network (such as a local or wide area network), other than transmission or reception apparatus.
- **8518** Microphones and stands therefor; loudspeakers, whether or not mounted in their enclosures; headphones and earphones, whether or not combined with a microphone, and sets consisting of a microphone and one or more loudspeakers; audio-frequency electric amplifiers; electric sound amplifier sets.
- **8519** Sound recording or sound reproducing apparatus.
- **8521** Video recording or reproducing apparatus, whether or not incorporating a video tuner
- **8523** Discs, tapes, solid-state non-volatile storage devices, ‘smart cards’ and other media for the recording of sound or of other phenomena, whether or not recorded, including matrices and masters for the production of discs, but excluding products of Chapter 37.
- **8525** Transmission apparatus for radiobroadcasting or television, whether or not incorporating reception apparatus or sound recording or reproducing apparatus; television cameras, digital cameras and video camera recorders.
- **8526** Radar apparatus, radio navigational aid apparatus and radio remote control apparatus
- **8527** Reception apparatus for radiobroadcasting, whether or not combined, in the same housing, with sound recording or reproducing apparatus or a clock.
- **8528** Monitors and projectors, not incorporating television reception apparatus; reception apparatus for television, whether or not incorporating radio-broadcast receivers or sound or video recording or reproducing apparatus.
- **8543** Electrical machines and apparatus, having individual functions.

- **8544** Insulated (including enamelled or anodised) wire, cable (including coaxial cable) and other insulated electric conductors, whether or not fitted with connectors; optical fibre cables, made up of individually sheathed fibres, whether or not assembled with electric conductors or fitted with connectors (note: this code can be spurious, as it can include passive components).

Following the definition, hardware imports from extra-EU countries and intra-EU imports are similar shares, with intra-EU imports only surpassing extra-EU ones by five percentage points (see *Figure* 9). When looking at country by country figures, the value of intra-EU imports is higher than extra-EU ones for most countries with some notable exceptions, namely for the Netherlands (EUR 80 551 944 490, namely EUR 62 381 300 510 higher than intra-EU imports), Ireland (EUR 4 851 072 314, namely EUR 1 958 955 443 higher than intra-EU imports), Hungary (EUR 6 753 493 869, namely EUR 1 031 473 773 higher than intra-EU imports), and the Czech Republic (EUR 16 628 116 800, namely EUR 2 543 176 067 higher than intra-EU imports).

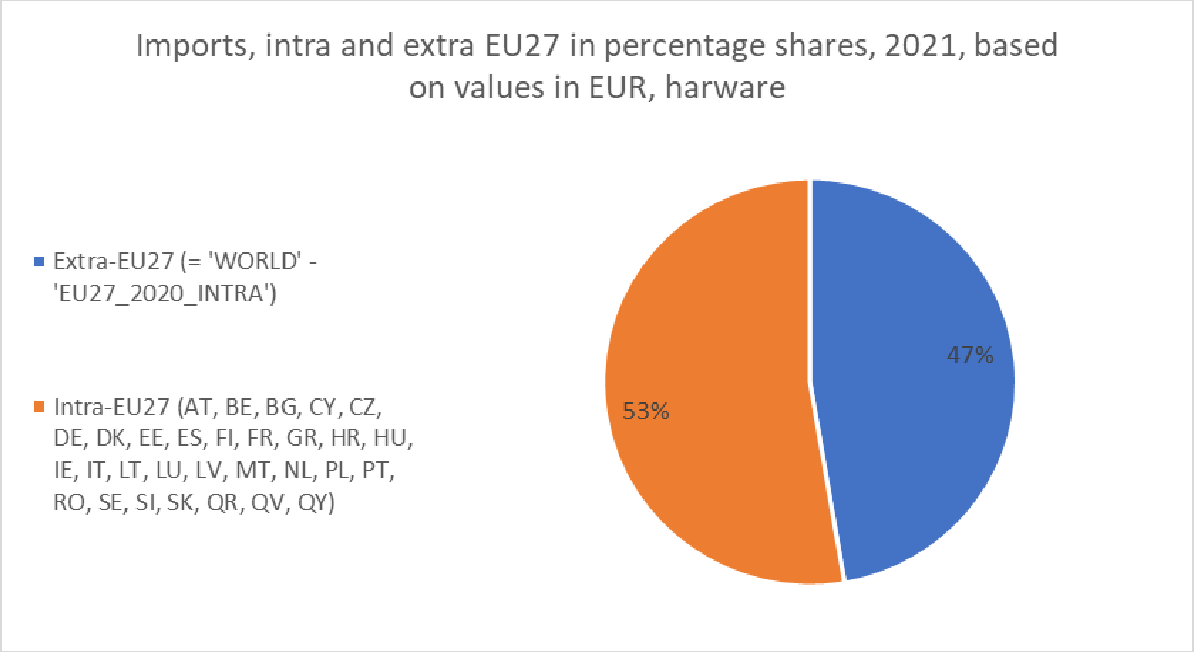


Figure 9: Imports, intra and extra EU27, in percentage shares based on values in EUR, 2021, hardware[61]

[61] Author's calculation based on COMEXT – Eurostat.

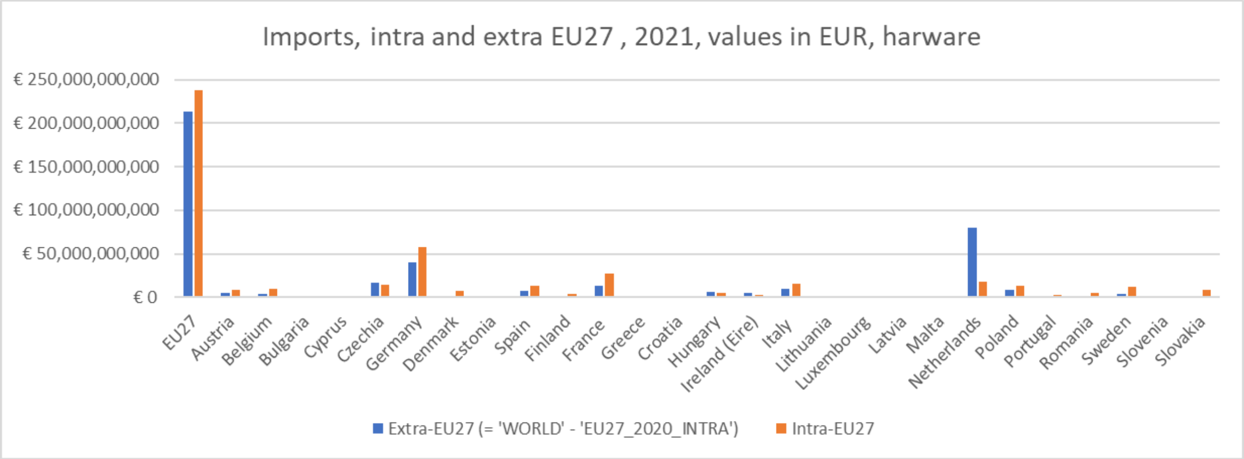


Figure 10: Imports, intra and extra EU27, values in EUR, 2021, hardware[62]

[62] Author's calculation based on COMEXT – Eurostat.

Aggregated market for products with digital elements

The global market for products with digital elements encompassing software and hardware has a total production value in of EUR 458 billion and turnover of EUR 550 billion in 2019,[63] if the hardware market is considered as only including the elements of the ICT-SC indicator. Considering the extended classification (ICT-EXT-ADJ), these values soar to EUR 1317 billion in production value and EUR 1485 billion in turnover for 2019.

The number of enterprises operating in this sector is 388 532 when considering the limited scope of ICT-SC and of 615 272 with a broader scope as defined by the ICT-EXT-ADJ indicator with a vast majority being SMEs according to the Project Team's estimations. Based on this data, these SMEs account for about 34.4 % of the turnover generated in the market for products with digital elements for 2019. *Table 25* and *Table 26* illustrate these statistics.

Indicators	Software (SD)	Hardware (ICT-SC)	Total
Production value (in billion EUR)	236	222	**458**
Turnover (in billion EUR)	265	285	**550**
% from SMEs	*41 %*[64]	*21.90 %*	***34.40 %***
Number of enterprises	365 759	22 773	**388 532**
% from SMEs	*99.70 %*[65]	*97.10 %*	***99.58 %***

Table 25: Aggregated indicators for global market for products with digital elements in 2019 in the EU (SD & ICT-SC)[66]

Indicators	Software (SD)	Hardware (ICT-EXT-ADJ)	Total
Production value (in EUR billion)	236	1 081	**1 317**
Turnover (in EUR billion)	265	1 220	**1 485**
% from SMEs	*41 %*[67]	*21.90 %*	***34.40 %***
Number of enterprises	365 759	249 513	**615 272**
% from SMEs	*99.70 %*[68]	*97.10%*	***99.58 %***

Table 26: Aggregated indicators for global market for products with digital elements in 2019 in the EU (SD & ICT-EXT-ADJ)[69]

[63] Second Interim Study Report N° 2019-0024 supporting the impact assessment.

[64] Percentage based on sample countries (France, Germany, Romania, Poland and Spain)

[65] Percentage based on sample countries (France, Germany, Romania, Poland and Spain)

[66] Eurostat: Second Interim Study Report N° 2019-0024 supporting the impact assessment

[67] Percentage based on sample countries (France, Germany, Romania, Poland and Spain) for ICT-SC)

[68] Percentage based on sample countries (France, Germany, Romania, Poland and Spain) for ICT-SC)

[69] Eurostat: Second Interim Study Report N° 2019-0024 supporting the impact assessment.

2. Summary of (aggregated) costs and benefits - preferred policy option

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Prevent internal market fragmentation	n/a	**Affected stakeholders:** • Economic operators, in particular hardware and software manufacturers • Public authorities (market surveillance authorities)
Enhanced security and transparency of products with digital elements	n/a	**Affected stakeholders:** • Users (B2B and B2C; public authorities)
Reduced number of cyber incidents	• By company/product: 20 to 33% of reduction of cybersecurity incidents • At aggregated level: approximately **EUR 180 to 290 billion annually for businesses** • No quantitative data for consumers and public authorities	**Affected stakeholders:** • Users (B2B and B2C; public authorities) • Economic operators, in particular hardware and software manufacturers (as regards reputational damage)
Improvement fundamental rights and in particular protection of personal data and privacy against breaches	n/a	**Affected stakeholders:** • Data subjects (citizens and consumers)
Increased turn-over due to conformity assessment		**Affected stakeholders:** • Notified bodies
Indirect benefits		
Decrease in risk mitigation costs (such as cyber insurance etc.)	n/a	**Affected stakeholders:** • Users (B2B and B2C; public authorities)
Higher uptake of digital solutions due to increased trust	n/a	**Affected stakeholders:** • Hardware and software manufacturers • Importers, distributors
Decrease in compliance costs, such as for operators of essential services under	• By company: o One off: 0.5 FTE (in average: EUR 33 280) for NIS entities	**Affected stakeholders:** • Business users • public authorities

the NIS Directive and entities subject to the GDPR	o Recurrent: 1-2% additional ICT security spending, for NIS entities (around 30 000 EUR by company, taking an average of 1.5%) • Aggregated: **EUR 6.95 bn**, with EUR 3.65 bn from one-off costs and EUR 3.3 bn recurrent costs.	
Increased global competitiveness by integrating security early in the development process and CE marking	n/a	**Affected stakeholders:** • Hardware and software manufacturers
Positive social impact, in particular reduced number of cybercrime	n/a	**Affected stakeholders:** • Businesses • Consumers • Public authorities • Citizens
Fewer incidents with a negative environmental impact	n/a	**Affected stakeholders:** • Society as a whole
Administrative cost savings related to the 'one in, one out' approach*		
Decrease in compliance costs, such as for operators of essential services under the NIS Directive and entities subject to the GDPR	• By company: o One off: 0.5 FTE (in average: EUR 33 280) for NIS entities o Recurrent: 1-2% additional ICT security spending, for NIS entities (around 30 000 EUR by company, taking an average of 1.5%) • Aggregated: **EUR 6.95 bn**, with EUR 3.65 bn from one-off costs and EUR 3.3 bn recurrent costs.	**Affected stakeholders:** • Business users • Public authorities
Prevent internal market fragmentation due to impending divergent national rules	n/a	**Affected stakeholders:** • Manufacturers of hardware and software

Table 27: Overview of Benefits (total for all provisions) – Preferred Option

*(1) Estimates are gross values relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section;(3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in adjustment costs, administrative costs, regulatory charges, enforcement costs, etc.;); (4) Cost savings related to the 'one in, one out' approach are detailed in Tool #58 and #59 of the 'better regulation' toolbox. * if relevant*

II. Overview of (aggregated) costs – Preferred option							
		Citizens/Consumers		**Businesses**		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
	Direct adjustment costs *(triggered by security requirements, information obligations)*	N.A.	N.A.	*Familiarisation with new requirements: N.A. *Information on security of products with digital elements: N.A. *Secure product development: • By company/product: + 30.5% secure product development costs (with BaU costs at 50%) • Aggregated: **EUR 13.13 billion** (together with life cycle approach, taking into account BaU costs of 50%) * Testing costs • self-assessment: in average 18 400 EUR by product • Aggregated cost: **EUR 7 bn** *Standardisation costs: N.A.		* Familiarisation with new requirements: N.A. * Appointing new market surveillance authorities (*if applicable*): EUR 1 600 000 per year * ENISA (EU Agency for Cybersecurity) : For handling reporting of vulnerabilities and incidents: 4.5 FTE	
	Direct administrative costs	N.A.	N.A.	*Conformity assessment (third party-assessment): • By company/product: o third-party assessment: in average EUR 25 000 • Aggregated: **EUR 1.1 billion** *Documentation and reporting (including creating and updating DoC and technical documentation, affixing CE marking,and reporting): • By product/company: +9% product development costs		N.A.	N.A.

				- Aggregated: **EUR 7.8 billion** (based on average product unit of EUR 140 000) * Accreditation framework: N.A. (for notified bodies)			
	Direct regulatory fees and charges	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	Direct enforcement costs	N.A.	N.A.	N.A.	N.A.	*Monitoring and enforcement new requirements: - Additional enforcement costs by product: in average EUR 12 500 - Aggregated **EUR 7.7 billion**	
	Indirect costs	* Higher initial prices of products with digital elements with digital elements		* Higher initial prices of products with digital elements		N.A.	N.A.
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	N.A.	N.A.	*Familiarisation with new requirements: N.A. *Information on security of products with digital elements: N.A. *Secure product development: EUR **13.13 billion** * Testing costs (self-assessment): - self-assessment: in average 18 400 EUR by product - Aggregated: **EUR 7 billion**			
	Indirect adjustment costs	N.A.	N.A.	N.A.	N.A.		
	Administrative costs (for offsetting)	N.A.	N.A.	*Certification: - By company/product: in average 25 000 EUR (BaU costs of 40% for hardware and 25% for software) - Aggregated: EUR **1.1 billion**			

				*Documentation and reporting: - By product/company: additional 9% of product development costs - **Aggregated: EUR 7.8 billion** (based on average product unit of EUR 140 000)		

Table 28: Overview of costs – Preferred option

ANNEX 4: ANALYTICAL METHODS

1. General approach

The appraisal of impacts by policy option relies on primary and secondary data collection. The collection of primary data included more specifically a workshop organised on 10 May 2022 by the contractors, an online targeted survey conducted by ICF SA, as well as a set of telephone interviews, including with SMEs. Furthermore, in the public consultation, respondents were asked questions about impacts on costs, competition and fundamental rights that are relevant for the impact assessment.

The online survey was launched on 16 May 2022 and at the moment of writing the impact assessment, the number of valid responses reached 24. In addition, the study team has conducted complementary interviews focused on cost estimates. Some additional consultations (with SMEs in particular) have been held as well.

Survey participants, workshop participants and interviewees have unanimously and consistently stressed the difficulties in providing exact figures. The main reason is that some of the requirements can be interpreted in different degrees of stringency which would impact costs in a very different way. Furthermore, the costs vary greatly depending on the type of product.

Quantitative cost estimations, even if gathered by the external Study, could not be triangulated and verified, and therefore have only been used for the cost aggregation to a very limited extent.

2. Key assumptions for the quantification of economic impacts

Several assumptions were made in order to quantify and compare the economic impacts of the different policy options.

Number of products on the market

In order to quantify the economic impacts of the policy options, the assumption was taken that **one company produces one product** as there is no possibility to know the number of products on the market. While this is an underestimation of the number of products, it is partially compensated by the fact that the number of companies is overestimated by using the ICT-EXT-ADJ indicator. Furthermore, the aggragted estimations have been made based on the assumption that all products currently on the market would be impacted, while under policy option 3 and 4, costs would actually occur for new products being placed on the market.

Cybersecurity is mostly adding costs on the design of a produt, therefore looking at the number of products (e.g. number of connected devices) on the market, where some data is available, would not have been relevant. It would have been relevant to know more precisely how many products are developed by the manufacturers of hardware and software products on the EU market. However, no such data exists.

While a methodological choice had to be made in the IA report, other possibilities to estimate the number of products are not excluded, such as looking at the basic analysis of a typical company structure – possibly by category of size and scopes. It could have been estimated how many products a company would develop according to its size, which would have lead to similar number of produts (when combined with a more conservative indicator). Given that more than 99% of the market are SMEs, with 94% being micro companies, most companies on the market would effectively not develop more than one or few products.

Alternative approaches for calculating the number of products have been considered for comparison, for instance such as dividing the turnover by the average cost of one unit of product with digital elements (EUR 140 000). This would however have led to an overestimation, as turnover also includes revenues. An alternative proxy could have been to take the investments in software/hardware to be divided by the average costs for one unit of product with digital elements (EUR 140 000)[70], but such data was not available.

Share of manufacturers already applying security requirements and testing

Furthermore, for quantifying the costs and benefits, it had to be assumed **how many manufacturers** would likely apply the full costs of secure product development, i.e. the percentage of companies that do not yet implement adequate security practices. Based on available data, it was estimated that currently **less than 50 %** of manufacturers have a systematic approach to product development in place.

This estimate was based on a number of assumptions and proxies, making most use of the scarce research and data available. More specifically: (i) according to a probe into a large number of products with digital elements developed by Microsoft, the introduction of secure development life cycles was found to reduce the number of vulnerabilities in a product by 66 %[71]; and (ii) based on the analysis of three different studies on the maturity of manufacturers of products with digital elements in the US (2010), Norway (2015) and Finland (2021), it was estimated that currently less than 50 % of manufacturers have a systematic approach to product development (see alos *Section 6.5)*.[72] While the study on US manufacturers is indeed less recent than the other two, there is evidence that shows that the overall picture has not changed since then: A very recent study on software vulnerabilities has concluded that "in 15 years, the vulnerability landscape hasn't changed; through the lens of the metrics in this paper we aren't making progress."[73], which suggests that there has been little (if any) improvement in how manufacturers approach product security. Therefore, it has been assumed that around 50% of manufacturers have currently adequate security practices in place for products with digital elements.

Cost estimations of secure product development

In order to aggregate the costs for integrating security in product development, a number of assumptions had to be made.

First, a percentage of additional product development costs had to be defined. The Venson model calibration[74] shows that the application of software security practices can impact the cost estimations ranging from a 19 % additional effort, on the first level of the security scale, to a 102 % additional effort, on the highest level of the scale. In order to classify the practices of secure software development, three broad categories were identified: (1)

[70] This approach was used in the *Impact Assessment for the AI Act.*

[71] Fonseca and Vieira (2013): "A Survey on Secure Software Development Lifecycles", Software Development Techniques for Constructive Information Systems Design, p. 12.

[72] Microsoft's Security Development Lifecycle or the Comprehensive, Lightweight Application Security Process (CLASP): Geer, D. (2010), p. 12-16; Martin Gilje Jaatun et al (2015): "Software Security Maturity in Public Organisations", ISC 2015: Proceedings of the 18th International Conference on Information Security - Volume 9290, September 2015, p. 120-138; Kalle Rindell et al (2021): "Security in agile software development: A practitioner survey", Information and Software Technology Volume 131, March 2021, 106488.

[73] Gueye and Mell (2021): "A Historical and Statistical Study of the Software Vulnerability Landscape", The Seventh International Conference on Advances and Trends in Software Engineering SOFTENG 2021, p. 1.

[74] Elaine Venson (2021): "The Effects of Required Security on Software Development Effort", A Dissertation Presented to the Faculty of the USC Graduate School University of Southern California.

Security Requirements, and Design, (2) Secure Coding and Security Tools, and (3) Security Verification, describing different security practices according to five security levels (Nominal; High; Very High; Extra High; Ultra High)[75]. It is estimated that the baseline security requirements aimed for in policy option 3 and 4 would equal to the security levels between "high" and "very high". Implementing security product and process requirements would represent additional product development costs **between 19 % and 42 %[76], hence an average of 30.5 %.**

Second, an average estimation had to be made for the **cost of a developing a product with digital elements**. According to the data available, hardware product development costs are estimated between USD 50 000 and USD 300 000,[77] and software product development are similarly estimated around the same range (USD 50 000 and USD 250 000).[78] Taking the median value, the average price/cost of the development of a product with digital elements could be estimated at USD 150 000, i.e. approximately **EUR 140 000**. This average development costs is comparable to other estimations, such as the one done for the unit cost of an AI system in the context of the Impact Assessment for the AI Act.[79] By using the coefficient proposed by Venson (taking the average of 30.5 %), the additional costs of security requirements for a product with digital elements could represent on average EUR 42 700 for one product with digital elements unit if this product has no security features in place.

[75] Elaine Venson (2021) [See "Table 4.4 Practices", page 106]

[76] According to the coefficient evidenced by the researcher (SECU), [See "Table 5.13" on page 150].

[77] https://orbit-kb.mit.edu/hc/en-us/articles/205586653-How-much-would-it-cost-to-develop-a-hardware-product-

[78] https://www.uptech.team/blog/software-development-costs#:~:text=Ultimately%2C%20it%20comes%20down%20to,than%20700%20hours%20to%20develop

[79] See SWD(2021) 84 final, IA accompanying the AI Act, one AI system unit is estimated to cost 170 000 EUR.

Annex 5: Background information on the problem definition

1. Piecemeal coverage of cybersecurity in EU policies and impending national intervention

While EU law lays down cybersecurity requirements for some categories of products with digital elements, the vast majority of hardware and software products is currently not covered by any EU legal act. Nonetheless, under the NLF, the EU's blueprint for product regulation, there is a small number of legal acts providing for product-related cybersecurity requirements. These include the (RED)[80] together with a recently adopted delegated regulation,[81] which cover IoT devices outfitted with a radio interface; the Medical Devices Regulation (MDR)[82] as well as the In Vitro Diagnostic Medical Devices Regulation,[83] which cover both tangible medical products as well as software; the relevant regulations on motor vehicles and their trailers, which also provide, among others, for empowerments the adoption of implementing or delegated acts concerning uniform procedures and technical specifications or updating technical requirements that may also concern cybersecurity-related aspects;[84]the Measuring Instruments Directive (MID),[85] which regulates measuring instruments or the Commission's recent proposals for a Machinery Regulation (MR),[86] as well as a Regulation laying down harmonised rules on AI.[87]

In addition, there are a few European product laws that provide some rules regarding the cybersecurity of products, albeit only in a *partial* manner: These include the Toy Safety Directive,[88] which regulates the safety of toys; the Machinery Directive,[89] which covers machinery products, including software ensuring safety functions; the Non-Automatic Weighing Instruments Directive;[90] the ATEX Directive,[91] which covers equipment and protective systems intended for use in potentially explosive atmospheres and covers some software related risks. An example of this partial coverage is the Non-Automatic Weighing Instruments Directive, which requires manufacturers to ensure that instruments are not adversely affected by external equipment connected to them and that instruments have no characteristics likely to facilitate fraudulent use, but lacks a more comprehensive approach to cybersecurity.

Most hardware, such as wired IoT devices or computer components, including chipsets, memory chips or processors, as well as the vast majority of software products, such as operating systems, user applications, server software or software libraries, are not covered by any European legal act.

The exploratory study contracted by the Commission and conducted in 2020-2021 to assess the need for horizontal cybersecurity requirements for products with digital

[80] RED: Directive 2014/53/EU.
[81] RED Delegated Act: C(2021) 7672 final supplementing RED, with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of RED.
[82] MDR: Regulation (EU) 2017/745.
[83] MDR: Regulation (EU) 2017/746.
[84] Regulation (EU) 2018/858 and Regulation (EU) 2019/2144
[85] Directive 2014/32/EU.
[86] Machinery Regulation (Proposal): COM(2021) 202 final.
[87] AI Act (Proposal): COM(2021) 206 final.
[88] Toy Safety Directive: 2009/48/EU.
[89] Machinery Directive: 2006/42/EU.
[90] Weighing Instruments Directive: 2014/31/EU.
[91] ATEX Directive 2014/34/EU.

elements conducted a **gap analysis**,[92] comparing the cybersecurity objectives of certification schemes set out in the Cybersecurity Act (Article 51)[93] against the identified cybersecurity-relevant requirements of **37 pieces of EU legislation** concerning ICT products, including all legislation related to the NLF, as well as legislation with a strong link with cybersecurity and data protection, which can affect even indirectly and to a limited extent manufacturers (e.g. the eIDAS Regulation, GDPR,[94] the NIS Directive, Radio Equipment Directive, General Product Safety Directive (GPSD)).[95]

Among the study's **most relevant findings of the gap analysis** the following could be mentioned:

- The **current EU legislative framework does not cover all security objectives** of the Cybersecurity Act, with **fragmentation and gaps** related to cybersecurity requirements for products with digital elements. This is illustrated below.

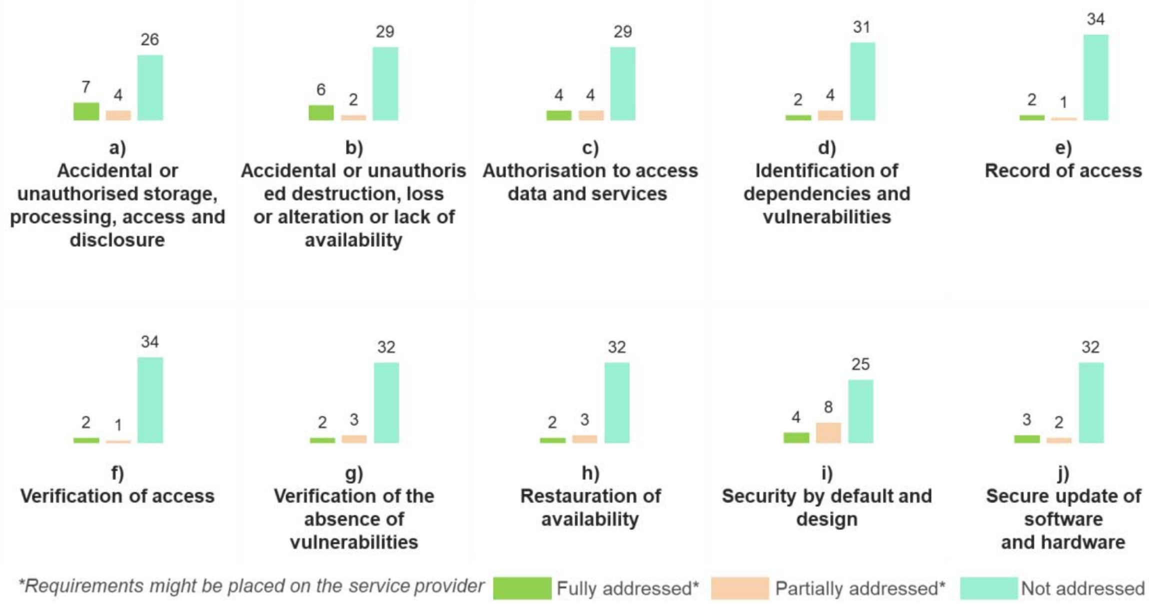


Figure 11: Gap analysis of the current EU legislative framework

- The legislation related to the **NLF does not address fully the cybersecurity requirements** for products with digital elements;
- Some pieces of legislation contain cybersecurity requirements that concern services rather than products and are therefore addressed to entities/service operators. While they can **indirectly affect the cybersecurity level of products with digital elements** used to operate the service, **they are not setting any clear obligations on the manufacturers of products with digital elements.** In such cases (for example GDPR obligations on data controllers or NIS obligations on operators of essential services), the way the service operators implement the respective

[92] Section 2.2 of the final report of the *Study on the need of Cybersecurity requirements for ICT products*, pages 52-61.

[93] To date, the Cybersecurity Act provides the most comprehensive set of cybersecurity requirements in EU law.

[94] The GDPR does not impose obligations to manufacturers of products but only to controllers processing personal data, yet the Regulation encourages them to respect the principle of data protection by design and by default when they develop new products.

[95] The gap analysis used as a basis the Cybersecurity Act because it is one of the most recent, up-to-date, and relevant EU legislation that covers cybersecurity for products with digital elements at broad spectrum. The cybersecurity objectives of Article 51 also provide a comprehensive list of high-level cybersecurity requirements for products with digital elements, such as protection against unauthorised access or disclosure of information, or verification, or to follow the security by default principle.

requirements (where there is some room for discretion) may affect in various ways the manufacturers of products with digital elements. This, in the absence of corresponding legislation setting requirements for security of products, may ultimately lead to misalignments of cybersecurity requirements and additional complexity for the manufacturers;

- There are **different levels of granularity in the definition of the scope** of products covered by the EU legislative framework that may lead to uneven burden on manufacturers of similar products or of products that may have similar importance from a cybersecurity point of view;
- There are **different levels of granularity** of **cybersecurity requirements** in the legislation in scope;
- Some pieces of legislation require the manufacturer or service provider to issue **"notifications" in case of a security breach or risk**,[96] which is an objective that is not present in the Cybersecurity Act, while for some other relevant pieces of legislation such notification obligation does not exist. Such notifications may ultimately have consequences on the cybersecurity of the products that may have been concerned by such incidents and, absent a horizontal approach on similar products, may lead to an uneven playing field for manufacturers and/or uneven protection of security; and
- The **safety aspects** of products in scope are overall **more addressed than the security aspect**s.[97]

Furthermore, the follow-up study[98] to support this impact assessment, contracted by the Commission in 2022, found in its preliminary in-depth analysis of relevant existing EU legislation, notably product-related, that requirements regarding software are very rarely covered by such legislation, and, even when this is the case, it is difficult to ascertain the precise cybersecurity requirements or obligations. Furthermore, it found that most of the pieces of legislation targeting product safety do not address the cybersecurity of the products falling under their scope. Moreover, the follow up study also analysed the interplay between the regulatory intervention and the Commission Data Act[99] proposal and concluded that the scope of the latter is different and hence the two pieces of legislation would be complementary.

See the more detailed preliminary analysis conducted by the study in Annex 8

2. Additional drivers not addressed by this intervention

In addition to the main drivers described in the problem definition, the Commission has identified a number of additional problem drivers that have an impact on the security of products with digital elements as well as on the understanding of users as regards such

[96] For example, Directive 2002/58/EC of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector provides that: *"In case of a particular risk of a breach of the security of the network, the provider of a publicly available electronic communications service must inform the subscribers concerning such risk and, where the risk lies outside the scope of the measures to be taken by the service provider, of any possible remedies, including an indication of the likely costs involved.". Also,* legislation connected to the NLF mandates the need to contact authorities in case a risk is identified on a product.

[97] Safety refers to the prevention of physical harm as a result of accidents, while security refers to the prevention of crime.

[98] Study supporting the Commission preparatory work for the Cyber Resilience Act – N° 2019-0024.

[99] Data Act Proposal: COM(2022) 68 final.

products. These are described only very briefly in the impact assessment itself, as the regulatory intervention would not address them.

Lack of bargaining power of users

As described above, products with digital elements markets are often characterised by the presence of a few large manufacturers as a result of *economies of scale* and *vendor lock-in*. For example, economies of scale play a significant role when it comes to producing semiconductors, as the manufacturing process is characterised by major fixed costs.[100] [101] While the development of large-scale software solutions, such as operating systems, also comes at a high cost, concentration in software markets is rather explained by vendor lock-in and high switching costs: As computer programmes are usually developed in such a way that they are compatible with a specific operating system, users cannot simply switch to another operating system when they are not satisfied with the security properties of the system that they have been using so far. For example, when it comes to Microsoft's operating system Windows, this has led the Commission to conclude that the company *"can behave independently of its end-customers"*.[102]

Irrespective of the reasons why some hardware and software products markets are controlled by a relatively small number of manufacturers, there are clear implications for the cybersecurity of the products offered on these markets and the security needs of users: businesses, such as operators of essential services under the NIS Directive, often lack the negotiating power to ensure that hardware and software suppliers provide products matching their own security needs.[103] [104] This is even more so the case when it comes to individual consumers.[105]

Lack of qualified security professionals

While products with digital elements markets do not provide the right incentives for hardware and software manufacturers to take cybersecurity seriously, manufacturers are also constrained by a shortage of information security professionals in the labour market. In a recent report, the European cybersecurity agency ENISA concludes that "there is a lack of skilled and qualified personnel in the labour market to work in cybersecurity roles and who can sufficiently address the range of cyber threats posed".[106] The International Information System Security Certification Consortium reports that in 2021 the gap in cybersecurity professionals in Europe amounted to 199 000 (up from 168 000 in 2020). In North America, where much of the hardware and software used in Europe is designed or developed, the skills gap amounted to 402 000 (up from 376 000 in 2020).[107] According to another recent survey, 55 % of businesses worldwide report unfilled information security vacancies, with 60 % of businesses reporting that it takes three months or longer to fill a vacancy.[108]

[100] Kenneth Flamm (2018): "Measuring Moore's Law: Evidence from Price, Cost, and Quality Indexes", Working Paper 24553, *NBER working paper series*.

[101] Statement by Executive Vice-President Margrethe Vestager on the Commission decision to accept commitments by Broadcom to ensure competition in chipset markets for modems and set-top boxes, 7 October 2020.

[102] Case COMP/C-3/37.792 Microsoft, p. 126.

[103] Tania Wallis (2020): "Achieving cybersecurity improvements through Enterprise Systems Engineering", *ASEC 2020 Proceedings*, p. 2.

[104] https://www.computerweekly.com/news/450415989/How-IT-can-be-more-defensible.

[105] Dutch Safety Board (2021), p. 89.

[106] ENISA (2021): "Addressing the skills shortage and gap through higher education", p. 5.

[107] (ISC)² (2021): "A Resilient Cybersecurity Profession Charts the Path Forward: (ISC)² Cybersecurity Workforce Study, 2021", p. 25.

[108] ISACA (2021): "State of Cybersecurity 2021. Part 1: Global Update on Workforce Efforts, Resources and Budgets", p. 8.

While a European initiative on security of products with digital elements cannot address deficiencies in the labour market, it is worth noting that the European Union has launched a number of initiatives to reduce the digital skills gap in general and the cybersecurity skills gap in particular. For instance, the Digital Europe Programme supports the development of a skilled talent pool of digital experts with EUR 580 million over the period 2021-2027, explicitly mentioning skills related to cybersecurity as one of its operational objectives. In addition, the European Cybersecurity Skills Framework developed by ENISA aims at creating a common understanding of the roles, competencies and skills required across the EU to alleviate the skills shortage in information security.[109]

Lack of cybersecurity awareness and skills of users

Users often choose products with digital elements ill-suited for their needs or configure them in such a way that they can be breached easily because they are either not fully aware of the risks associated with the products they deploy or lack the necessary technical skills. According to a recent survey amongst 3 000 consumers, while 69 % consider themselves as being good or very good in protecting their accounts, two thirds reuse passwords either for some or sometimes even for all their accounts. In addition, only one third are able to correctly define a set of basic internet security terms.[110] A study from June this year has surveyed 553 parents in the UK "that families do not consider home IoT devices to be significantly different in terms of threats than more traditional home computers, and believe the major risks to be largely mitigated through consumer protection regulation. As a result, parents focus on teaching being careful with devices to prolong device life use, exposing their families to additional security risks and modeling incorrect security behaviors to their children."[111] The lack of awareness not only applies to consumers but also to business users. For example, only half of company leaders and a third of employees acknowledge the risk that cybercrime poses to their organisations.[112]

Update habits are one way to measure the awareness of users of the risks associated with the technology that they use. For instance, Android users are known to delay or even entirely forgo updating applications installed on their systems despite the fact that updates are essential to patching critical holes in users' mobile devices.[113] It does not come as a surprise that generally speaking inexperienced users are much less likely to install crucial security updates than proficient IT users.[114] Similarly, companies regularly fail to patch critical holes in their networks, with a large number of incidents being the result of unpatched but long known vulnerabilities in products.[115] When it comes to cybersecurity skills, even companies regularly fail to configure their systems correctly. For example, cybersecurity incidents following a misconfiguration of cloud systems were responsible for the exposure of more than 33 billion data records in 2018 and 2019. Organisations mostly affected were tech companies, health care providers and governments.[116]

[109] For more details, see https://www.enisa.europa.eu/topics/cybersecurity-education/european-cybersecurity-skills-framework.

[110] Google/Harris Poll (2019) https://services.google.com/fh/files/blogs/google_security_infographic.pdf.

[111] Sarah Turner, Nandita Pattnaik, Jason R.C. Nurse, Shujun Li (2022): '"You Just Assume It Is In There, I Guess": UK Families' Application And Knowledge Of Smart Home Cyber Security'.

[112] Grayson Kemper (2019): "Improving employees' cyber security awareness", *Computer Fraud & Security, Volume 2019*, Issue 8, August 2019, Pages 11-14.

[113] M. Oltrogge, Y. Acar, S. Dechand, M. Smith, and S. Fahl: "To Pin or Not to Pin—Helping App Developers Bullet Proof Their TLS Connections" in Proceedings of the 24th USENIX Conference on Security Symposium, ser. SEC'15. Berkeley, CA, USA: USENIX Association, 2015, p. 240.

[114] Mathur, Malkin et al. (2018): "Quantifying Users' Beliefs about Software Updates", p. 1.

[115] Check Point (2021): "Cyber Security Report", p. 55.

[116] DivvyCloud (2020): "2020 Cloud Misconfigurations Report. Breaches Caused by Cloud Misconfigurations Cost Enterprises Nearly $5 Trillion in 2018 and 2019", p. 4 and 10.

The EU is addressing digital skills through the Digital Europe Programme, which supports the development of a skilled talent pool of digital experts with EUR 580 million over the period 2021-2027, explicitly mentioning skills related to cybersecurity as one of its operational objectives. In addition, ENISA together with the Commission and the Member States organises European Cyber Security Month on an annual basis to promote cybersecurity among EU citizens and organisations and provide up-to-date online security information through awareness raising activities and sharing of good practices.

While awareness and lack of skills are important sources of incidents, manufacturers often do too little ensure that their products can be used securely "out of the box" by inexperienced users. One way to help inexperienced users is to ship products with all security settings set to maximum (*security by default*) or by automatically applying security updates without requiring an intervention by the user.

Asked in the public consultation to which extent consumers understand the cybersecurity properties they should expect from products and to which extent they have the skills to operate them securely, consumers organisations gave a rating of only 1.67 (on a scale from 1 to 5).

ANNEX 6: GLOBAL DEVELOPMENTS

1. United States

In May 2021, an Executive Order (EO)[117] was issued by the US President, charging operational federal agencies, including the National Institute of Standards and Technology (NIST) in the US Department of Commerce, with developing guidelines for enhancing cybersecurity through a variety of initiatives related to the security and integrity of the software supply chain.[118]

The EO established a detailed plan for taking steps to secure the federal software supply chain and called for NIST to publish guidelines for establishing best practices to detect vulnerabilities and requirements that all critical software delivered to government customers, including a software bill of materials to ensure transparency of supply chain. It also included milestones that agencies must meet to demonstrate progress toward the goals. In 2021, NIST also initiated a pilot program on cybersecurity labelling for IoT products. In the same year, as required by the EO, NIST released its definition of critical software and published guidance for outlining security measures for critical software use and minimum standards for manufacturers' testing of their software source code. In mid-2021, the National Telecommunications and Information Administration (NTIA) released a minimum definition of a software bill of materials (SBOM). In February 2022, NIST issued guidance for supply chain security.[119]

In July 2021, both the House of Representatives and the Senate of United States of America began drafting legislation in two separate committees. In particular, the House's Homeland Security Committee introduced seven bipartisan bills, five of which focused strictly on strengthening cybersecurity, while the Senate's Homeland Security and Governmental Affairs Committee introduced 'The Supply Chain Security Training Act,' calling it a *'bipartisan legislation to help protect against cybersecurity threats and other technological supply chain security vulnerabilities that arise when the federal government purchases services, equipment or products.'*[120]

Recently, the US Department of Defense released a report titled 'Securing Defense Critical Supply Chains',[121] where it presents its priorities and capabilities to make stronger the USA industrial base and to create a network of domestic and applied supply chains to meet national security needs. In particular, the report identifies cyber posture, characterised by industrial security, counterintelligence and cybersecurity - as one of the strategic enablers necessary to build overall supply chain resilience.[122]

2. United Kingdom

[117] (EO) 14028 on Improving the Nation's Cybersecurity:

[118] The EO stated that: '*Incremental improvements will not give us the security we need; instead, the Federal Government needs to make bold changes and significant investments in order to defend the vital institutions that underpin the American way of life. The Federal Government must bring to bear the full scope of its authorities and resources to protect and secure its computer systems, whether they are cloud-based, on-premises, or hybrid. The scope of protection and security must include systems that process data (information technology (IT)) and those that run the vital machinery that ensures our safety (operational technology (OT)).*'

[119] Software Supply Chain Security Guidance Under Executive Order (EO) 14028 Section 4e.

[120] https://www.hsgac.senate.gov/media/majority-media/after-passing-house-peters-and-johnson-legislation-to-help-secure-federal-information-technology-supply-chains-against-security-threats-heads-to-president-to-be-signed-into-law.

[121] https://media.defense.gov/2022/Feb/24/2002944158/-1/-1/1/DOD-EO-14017-REPORT-SECURING-DEFENSE-CRITICAL-SUPPLY-CHAINS.PDF

[122] See Hogan Lovells (2022), The department of Defense's report on Securing Defense-Critical Supply Chains" April 12

Some developments in terms of supply chain security have been furthered also in the United Kingdom. In May 2021, the U.K. government announced that it was seeking advice on defending against digital supply chain attacks from organisations that either consume IT services, or Managed Service Providers that provide software and services. While the feedback has not been released to the public yet, the U.K. government has noted that it will result in the re-evaluation of supply chain risks, reviewing policies, and likely implementing new guidelines and frameworks to strengthen specific areas of digital supply chain security. It could also mean the introduction of new, country-wide legislation for software firms and IT service providers. Moreover, following a work carried out in 2018 on telecom supply chain security, in May 2022, the Department for Digital, Culture, Media, and Sport (DCMS) opened up a survey that closed in early July and invited comments from industry experts and technology organisations on stepping up supply chain security across the UK.

3. Asia: examples of Japan and Singapore

The Ministry of Economy, Trade and Industry of Japan (METI) envisages the development of a super-smart society in which cyberspace and physical space are integrated in a sophisticated manner, the so-called "Society 5.0". To meet the cybersecurity challenges stemming from this scenario, the Japanese government published the Cyber-Physical Security Framework (CPSF) Ver1.0 on April 18, 2019, which outlines security measures against new risks in Society 5.0 and propose a “Three-Layer Approach” to articulate risks and appropriate measures in the whole supply chain.[123] The second layer is represented by the actual connection of the physical and cyberspace, namely the IoT systems themselves. In this context, the METI published in March 2020 a draft of the “IoT Security Safety Framework” with a guideline on how to guarantee security for IoT devices and systems. In this context, METI introduced a method for classifying IoT devices and systems based on their risk profiles. IoT devices are classified alongside two axes: (1) the degree of difficulty of recovery from the incidents; (2) perspective of economic impact from the incident.

The Cybersecurity Labelling Scheme (CLS) is an instrument issued by the Cyber Security Agency of Singapore to manage the cybersecurity of consumer IoT products. The Cybersecurity Labelling Scheme is a voluntary scheme, except for Wi-Fi Routers, for which it is mandatory to meet the baseline cybersecurity requirements. The CLS covers Wi-Fi Routers and Smart Home Hubs, and it is open to all other categories of IoT devices. The labelling scheme foresees different level similar to the assurance levels in EU certification schemes. The highest level involved third-party testing.

[123] See METI (2019), Cyber/Physical Security Framework (CPSF) Formulated. Available here.

ANNEX 7: COMPARISON OF THE RED DELEGATED REGULATION VS POLICY OPTION 4 (COMPREHENSIVE HORIZONTAL REGULATION FOR ALL PRODUCTS WITH DIGITAL ELEMENTS)

	Horizontal cybersecurity requirements for all products with digital elements *(including inter-connected radio-equipment)*	**RED Delegated Regulation (RED DA)**
Scope		
internet-connected radio equipment and wearable radio equipment ('wireless'), including laptops, smartphones and tablets	yes	yes
Wired-only connected products	yes	no
Non-embedded (standalone) software	yes	no
Non-radio components (e.g. processors)	yes	no
Requirements & obligations		
Cybersecurity dimension (protection of network, ensure data protection and relevant aspects on privacy and fraud dimension	yes (more specific – e.g. addressing cybersecurity risks to availability, integrity, confidentiality; vulnerability handling, transparency and information to users' obligations, etc.; the more specific requirements would fit into the very generic cybersecurity requirements of RED Delegated Regulation)	yes (very generic)
Duty of care and whole life cycle	yes	no
Conformity assessment		
Conformity assessment	Self-assessment, and third-party assessment for a narrow share of critical products, and potentially mandatory EU certification for highly critical products	Self-assessment

Table 28: Comparison RED Delegated Regulation vs Policy option 4

ANNEX 8: EXTRACT FROM THE PRELIMINARY FINDINGS OF THE STUDY SUPPORTING THE COMMISSION PREPARATORY WORK FOR THE CYBER RESILIENCE ACT (N° 2019-0024)

- **A focus on software**

The analysis revealed that software is rarely explicitly mentioned in the legislative texts of relevant legislative acts, and even when this is the case, it might be difficult to ascertain the relative cybersecurity requirements or obligations. This is particularly true for pieces of legislation that are currently under review, such as the Machinery Directive - which makes limited references to hardware and software when talking about control systems (Essential Health and Safety Requirement 1.2) - and the GPSD - which does not currently provide enough legal certainty about the coverage of the specific features of new technology products, such as software updates or the evolving nature of new technologies.

The EC aimed to update these pieces of legislation to address challenges brought by new technological developments,[124] hence clarifying the role of software with regard to the overall product functioning and its possible impact on health and safety of consumers. To do so, the **Proposal for a Regulation on Machinery Products** further clarifies the definition of 'safety component' to include not only physical components but also non-physical components such as software performing a safety function and placed independently on the market (Article 3(3)). Furthermore, it adapts the definition of 'machinery', including machinery missing only the upload of a software intended for the specific application of the machinery under it and not under the definition of partly completed machinery (Article 3(1f)). However, it must be noted that pursuant to Article 2(2m) it would not apply to electrical and electronic products falling within the scope of application of Directive 2014/35/EU or Directive 2014/53/EU, such as household appliances, audio/video equipment and information technology equipment.[125] The **Proposal for a Regulation on General Product Safety (GPSR)** updates the definition of 'product' included in Article 3(1) to *'items that are interconnected or not to other items'*, and it expands the criteria for assessing the safety of products (Article 7h) to include the appropriate cybersecurity features necessary to protect the product against external influence. It is also worth mentioning that the GPSR will take over the role of 'safety net' (as the GPSD before) with regard to non-harmonised consumer products and to the harmonised consumer products for the aspects that are not covered by harmonised legislation.[126]

Software is also mentioned in the **AI Act** when defining AI systems (Article 3). The proposal directly links AI systems to software by clarifying that this software possesses key functional characteristics (listed in Annex I) and aims to accomplish a set of human-defined objectives.

The reference to software is more explicit in other pieces of existing EU product safety legislation. This is the case for: the **RED**, which covers software "*allowing radio equipment to be used as intended*" (Article 4); the **MDR**, which already reflects the ongoing digitalisation process and covers software (Article 2), while addressing the

[124] In this regard, it is possible to refer to: (i)Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council. P.3; and (ii) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on machinery products. P.1

[125] This input was shared by Mark D. Cole, Professor for Media and Telecommunication Law at the University of Luxembourg, member of the Advisory Board.

[126] This input was shared by Mark D. Cole, Professor for Media and Telecommunication Law at the University of Luxembourg, member of the Advisory Board.

cybersecurity of both hardware and software; and the **Measuring Instrument Directive** (MID) which mentions software within the requirements placed on the products falling under its scope and defines specific conformity assessment modules for electronic systems or systems containing software (see Annex I, II, VIII and IX).

Furthermore, other pieces of EU legislation refer to software in their provisions. For instance, the **Consumer Sales Directive** (CSD) includes in its scope the notion of goods with digital elements, and thus applies to any digital content or digital service. Recital 14 of the CSD clarifies that digital content incorporated in or inter-connected with a product under the scope *"can be any data which are produced and supplied in digital form, such as operating systems, applications and any other software*" regardless of the time of installation (before or after the sale). Software is also used to define compatibility and interoperability aspects of the goods falling under the CSD (Article 2). Another example of reference to software is the **Market Surveillance Services Directive** (MSD) which mandates manufacturers (Article 15) to provide, upon request of the approval authorities, information about software and algorithm which are necessary to demonstrate the conformity of a vehicle, system, component or separate technical unit. Software is also included in the notion of a product (Article 3) provided by the **eIDAS regulation** which defines product as "*hardware or software, or relevant components of hardware or software, which are intended to be used for the provision of trust services".*

In conclusion, the new challenges brought by new technological developments prompted the EC to update some pieces of legislation, by clarifying the role of software within their provisions (e.g., MR, GPSR, AI Act) in light of their relevance for security of networks and rights of individuals in an increasingly connected environment. Software is considered by several pieces of EU legislation either as a way to define the products falling under their scope (e.g., MDR, RED, CSD, eIDAS) or to highlight certain characteristics of products which deserve particular attention from their manufacturers (e.g., MID, MSD).

- **Approach to safety and security in the EU legislative framework on products**

The exploratory study concluded that the EU legislation on products focuses mainly on safety rather than security (see finding #7). This finding appears to be consistent with the intent of the EC to align the EU regulatory framework on products with the reference provisions set by Decision 768/2008/EC[127](part of the NLF) which placed obligations on economic operators along the supply chain (e.g., manufacturers, importers, distributors) to ensure the health and safety of consumers.[128] However, the NLF does not contain provisions mandating economic operators to account for cybersecurity during the risk assessment and subsequent identification of NLF certification modules and self-declaration. As a result, security is accounted for only in some pieces of legislation which do not set horizontal cybersecurity requirements.

Most of the pieces of legislation targeting product safety do not address the cybersecurity of products falling under their scope. For instance, the **Recreational Craft and Personal Watercraft Directive** (RRD) does not place any cybersecurity requirements on the products falling under the scope of the analysis nor on the main economic operators considered in Chapter II of the Directive. The essential requirements laid down in Annex I of the RRD mainly concern safety aspects such as the identification, the structure, the stability and other physical aspects of the products in scope. The **Pressure Equipment Directive** (PED) represents another example of a directive which covers safety without considering the security (and cybersecurity) aspect. The PED contains (Annex I) a set of

[127] Information available at: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_fr

[128] For instance, Annex I - Reference provisions for community harmonisation legislation for products, Article R2 (4 and 7), Article R4 (4 and 6) and Article R5 (2).

general, design, manufacturing and other requirements that focus strictly on safety without safeguards aimed at addressing the cybersecurity of the measuring instruments.

Over the past years, the EC has been seeking to address the new challenges on consumer safety posed by new digital technologies (e.g., software, AI, IoT) by putting forward pieces of EU product legislation which clearly addressed cybersecurity when connected to consumer safety. When looking at sector-specific regulation, it is possible to refer to two examples, namely the Measuring Instruments Directive (MID)[129] and the MDR. Within Annex I, the **MID** includes essential requirements both on suitability of the equipment (ESHR 7), defining additional precautions to be used when the product is associated with a software and, on protection against corruption (ESHR 8). The requirement addresses the risk for a measuring instrument to be connected with another device and to be subject to an inadmissible influence. The **MDR** lays down essential requirements for medical devices that function through an electronic system or that are software themselves[130]. These requirements mandate manufacturers to develop and build their products by applying risk management principles and by setting out requirements concerning IT security measures. It is important to point out that the MDR does not clarify which risks the regulation is seeking to address. Particularly, the MDR does not distinguish between functionality and safety risks as the poor functioning of a medical device has usually a direct (negative) effect on the health and safety of its user. It follows that the requirements set by the regulation focus on the reliable performance of the device[131]. The most relevant requirements accounting for the cybersecurity of the products falling under the scope of the MDR are No. 14 (Construction of devices and interaction with their environment) and No. 17 (Electronic programmable systems), both included in Annex I of the regulation. Additionally, considering more horizontal pieces of legislation, the **RED** took another step forward in addressing cyber-related risks of inter-connected devices and wearables, with the RED Delegated Act which shall apply form 1 August 2024. In fact, the Directive foresees two requirements in Article 3(d), (e) and (f) which aim to address network protection and incorporate safeguards into products so to protect users' privacy and personal data as well as to protect them against fraud.

More recently, the **GPSR** proposal addresses cybersecurity risks that have an impact on the safety of consumers by mandating products to possess cybersecurity features (Article 7h) that can protect them from external influences (e.g., hacking). However, it is worth pointing out that manufacturers are mandated to consider cybersecurity risk only if Article 6(1a) on harmonised European standards and Article 6(1b) on national requirements do not apply. Furthermore, the **Machinery Regulation proposal** (MR**)** mandates new requirements (Annex III – 1.1.9 and 1.2.1) on the protection of machinery against corruption and unauthorised access. Particularly, while introducing the concept of security by design for machinery and control systems (i.e., those connected should be designed in such a way to minimise their exposition to hazardous situations), the requirements also stress the importance in the identification and subsequent protection of software and data that impact on the compliance of the machinery with health and safety requirements.

On the other hand, when it comes to certain existing pieces of EU legislation discussion are ongoing on whether they should take into account cybersecurity aspects, such as the **Toy Safety Directive** (TSD). In this regard, the European Parliament expressed concerns in relation to the new risks posed by connected toys, particularly when they pose threat to child safety, security, privacy and mental health. Furthermore, while pointing out that connected toys show inadequate level of security, with no or limited measures to prevent

[129] MID: Directive 2014/32/EU.

[130] https://ec.europa.eu/health/system/files/2022-01/md_cybersecurity_en.pdf, p. 4.

[131] Wendenhorst C. (2020). Safety and Liability Related Aspects of Software, p. 51.

cyber threats, the European Parliament called on the EC by updating the TSD or exploring other options to increase consumer protection such as the adoption of a horizontal piece of legislation on cybersecurity requirements for connected products and associated services[132]. However, it is important to note that the Delegated Regulation adopted under the RED in October 2021 partially addressed the need for cybersecurity requirements on wireless toys (Article 1(2)c).

In conclusion, while recognising the efforts put forward by the EC in relation to an increased **cybersecurity of products marketed within the EU, security, and more specifically cybersecurity, still does not appear to be broadly embedded in the EU legislation on product safety**[133]. The requirements currently in place target specific types of products (e.g., medical devices, measuring instruments) and/or are cross-sectoral but focus only on digital devices with certain characteristics (e.g., wireless).

- **Product life cycle approach**

The EU legislation on products currently relies on the concept of '*placing a product on the market*'. This notion appears to be challenged by new technological developments that allow products to evolve after this moment in time. For instance, software updates can change the functionalities of the product on which the software operates.

Discussions on whether the NLF could be updated to incorporate the concept of a product life cycle approach are currently ongoing. However, as highlighted by an expert supporting the study, stakeholders have suggested that the focus of the NLF should remain on setting common reference provisions for placing a product on the market, with changes post-market placement being better addressed on an *ad-hoc basis* by individual pieces of legislation. Another possibility raised by stakeholders is to accommodate these developments by amending the suite of conformity assessment modules of the NLF, for instance by introducing a new component related to post-market placement verification. All in all, while being currently under evaluation, the NLF is not yet subject of a proposal to update and modernise it (i.e. no impact assessment is currently planned).

As a notable exception to this static view of product compliance, the **MDR** foresees (in Annex I (3)) a specific requirement placed on manufacturers to establish, implement, document and maintain a risk management system for their products, meaning a process throughout the entire life cycle of a device, requiring regular systematic updating. Similarly, but more recently, the **AI Act** proposal requires high-risk AI systems to be subject to a risk management system (Article 9). Moreover, the proposal sets requirements on record-keeping (Article 12) and accuracy, robustness and cybersecurity which shall also take into consideration the life cycle of high-risk AI systems. Furthermore, the activation of the **delegated acts under the RED** addresses software updates.

Additionally, draft legislative proposals pertaining to the updating of EU harmonisation legislation, often take more of a product life cycle approach, reflecting the fact that change in products may occur post market placement, either due to software updates/upgrades or due to the circular economy. For instance, the **GPSD** is currently under revision to accommodate the ever-evolving nature of digital technologies (i.e., GPDR proposal). In fact, the Sub-group on AI, connected devices and other challenges for new technologies to the Consumer Safety Network recommended that the revision of the GPSD should clarify that products should be safe during their whole lifespan to accommodate for the new risks

[132] European Parliament (2021). Report on the implementation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (Toy Safety Directive).

[133] It is worth mentioning that, as highlighted by Mark D. Cole of the Advisory Board, in the Impact Assessment for the GPSR (SWD(2021) 168 final) it is stated that gaps in sectoral legislation (such as wired devices not covered by the RED delegated act) might be covered by the GPSR in its role of safety net.

brought by digital technologies. Against this background, the **GPSR** put emphasis on the need for the product to be safe over its entire lifespan. In this regard, Article 12 (cases in which obligations of manufacturers apply to other economic operators) defines circumstances under which any economic operator that modifies *"a product in such a way that conformity with the requirements of this Regulation may be affected, should be considered to be the manufacturer and should assume the obligations of the manufacturer".*[134] The **MR** proposal also provides an example of how some aspects of changes (e.g., to software updates, AI and machine learning technologies) to products post-placement can already be addressed at the moment a product is placed on the market. The MR requires an upfront risk assessment as to any potential changes post-market if these risks bring a product into non-compliance with the essential requirements (Annex III -1c). Currently, there are significant challenges related to the issue of built-in obsolescence (i.e. products are designed to be replaced in a certain timeframe and will therefore no longer be supported). Within this context, there is a key question of 'for how long (per product type) economic operators should provide security updates.[135]

- **Responsibilities set along the value chain**

Since its adoption in 2008, the NLF represented an important step forward in the strengthening of the EU Single Market. The NLF identifies the economic operators having an impact on product safety, while also defining their respective responsibilities and obligations within the value chain. Consequently, the sectoral and product-focused NLF-aligned legislation followed this framework to guarantee legal certainty to consumers and businesses operating within the Single Market. Nevertheless, new technological development and the shift toward greener and circular economy brought a broader set of economic operators to play a relevant role within the value chain. The EC is conducting an evaluation, assessing whether the NLF continues to be fit for purpose in the current economic reality and changing digital environment.[136] [137]

The 2019 **Market Surveillance Regulation (MSR)**, which came into effect in 2022, introduced for most NLF-aligned laws (see Article 4(5)) the requirement for an EU-based economic operator in order to place a product on the market. One of the options is to contract an authorised representative (which was actually already defined in the NLF), while another is to use a fulfilment service provider (newly defined in the MSR). However, manufacturers/importers are not mandated to use an authorised representative or fulfilment service provider.[138] This regulation represented a first step to address the challenges faced by market surveillance authorities when tracing non-compliant products imported into the Union and identifying the responsible entity within their jurisdiction.

The **MDR** represents a comprehensive piece of legislation covering all economic operators in the value chain such as manufacturers[139] (Chapter II, III and V), importers (Article 13), authorised representatives (Article 11) and distributors (Article 14). It is worth noting that manufacturers encompass also software manufacturers as long as their products have a medical purpose and thus can be classified as a medical software. While mainly targeting

[134] It is worth noting that the modification creates new obligations on other operators only when such modification is 'substantial'. The same article describes the criteria that should be met to consider modification as 'substantial', namely: (a) the modification changes the intended functions, type or performance of the product in a manner which was not foreseen in the initial risk assessment of the product; (b) the nature of the hazard has changed or the level of risk has increased because of the modification; and (c) the changes have not been made by the consumer for their own use.

[135] This input was shared by Mark Whittle Director of CSES Europe, member of the Advisory Board.

[136] See https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12654-Industrial-products-evaluation-of-the-new-legislative-framework_en

[137] Information on the supporting study is available at: https://op.europa.eu/en/publication-detail/-/publication/f26b695f-cce7-11ec-a95f-01aa75ed71a1/language-en

[138] This input was shared by Mark Whittle Director of CSES Europe, member of the Advisory Board.

[139] Including the natural or legal person who fully refurbishes a device.

the manufacturers of medical devices, the MDR sets obligations on several economic operators to make sure that there are always multiple stakeholders responsible for provisions set by the regulation, particularly when products are manufactured from non-EU countries. Similarly, the RED stresses that all economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market radio equipment which is in conformity with the Directive and therefore it is necessary to provide for a clear and proportionate distribution of obligations (recital 27).

On the other hand, responsibilities along the value chain had to be further clarified within the proposals for some pieces of legislation currently under review, as in the case of the **GPSR** (recital 24) and the **MR** (recital 25). It is interesting to note that the latter also clarifies that when a machinery is substantially modified according to the definition, the one that modifies the machinery becomes manufacturer and must comply with the relevant obligations (recital 36 and Article 15). Furthermore, as the complexity of the machinery supply chain is increasing, there is a general obligation of cooperation of third parties involved in the machinery supply chain, other than economic operators.

It is also worth noting that the **NIS2** proposal, while not covering any product, addresses, for the first time, cybersecurity of the digital supply chain (of special importance in the case of the IoT) (recital 43 and Article 5(2a)).

- **Conformity Assessment**

Looking at the conformity assessment procedures, in general significant emphasis is put on the importance of standardisation in an effort to ensure greater conformity. In the context of this study, a comparative analysis of conformity assessment modules was done to elucidate the main approaches in view of studying the most similar and suitable modules for the planned initiative.

The GPSD and GPSR proposal opt for a presumption of safety in case common standards as specified in the Directive are applied. Similarly, the MDR (Article 7) and MR proposal (Article 17) adopt a presumption of conformity of machinery when manufacturers apply harmonised standards, with self-assessment through Module A provided as default option, but not for high-risk machinery.

In other cases, conformity assessment procedures as well as the involvement of third parties, greatly depends on the product classification adopted in the legislation: for instance, this is the case for the MDR (recital 60) as well as for the proposal on AI Act.

- **Market surveillance**

Concerning market surveillance rules, the pieces of legislation analysed usually contain dedicated articles. However, it is worth mentioning that only some of them explicitly address certain aspects concerning post-market surveillance. This is particularly important when looking at new technologies, as these pose challenges related to the notion of placing a product on the market and the monitoring of its compliance with obligations and requirements post-market placement (i.e., life cycle approach). Products including new technologies can evolve and their safety features may change via software updates or machine learning after they have been placed on the market. For instance, AI Act proposal, sets out monitoring and reporting obligations for providers of AI systems regarding post-market monitoring and reporting, as well as the investigating of AI-related incidents and malfunctioning. Market surveillance authorities would also control the market and investigate compliance with the obligations and requirements for all high-risk AI systems already placed on the market (Article 61).

It is worth mentioning that the new MSR,[140] which amended the 2008 market surveillance provisions under Regulation (EC) 765/2008, aims at reinforcing the effectiveness of market surveillance in the EU, with an eye on addressing challenges posed by the digital age. As set out in Article 2, the Regulation applies to all products that are subject to one of the 70 EU safety instruments listed in Annex I - including the RED, the MDR, the MD and the TSD - in the absence of more specific rules on market surveillance; however, the provisions requiring an EU-based economic operator.

[140] MSR: Regulation (EU) 2019/1020.

ANNEX 9: TABLE ILLUSTRATING THE POTENTIAL INTERPLAY BETWEEN A HORIZONTAL REGULATORY INTERVENTION (NOTABLY POLICY OPTION 4) WITH EXISTING PRODUCT-RELATED LEGISLATION

Legislation	Potential relationship between the existing product legislation and a comprehensive horizontal regulatory intervention (policy option 4)	Digital dimension	Cybersecurity elements covered	Possibility to opt for self-assessment when harmonised standards are applied	Modules	Types of products + other related remarks	Examples of types of products	NLF	Main relevant articles
Measuring Instruments - Directive 2014/32/EU	No amendments necessary, intervention to complement. Essential requirements for suitability and protection against corruption	yes	yes (measuring instruments have embedded software)	no	All except A1, C1	Measuring instruments	Water meters, gas meters, thermal energy meters, taximeters, automatic weighing instruments etc.	yes	17, 19(2), 30
Radio equipment - Directive 2014/53/EU + Delegated Regulation	RED DA to be implemented until the horizontal cybersecurity rules start applying. The upcoming legislation would then provide more specific cybersecurity requirements and it can be considered that the RED DA cybersecurity requirements would become	yes	yes	yes	A, B+C, H	All radio equipment	Wi-Fi routers, AM/FM radios, TVs, mobile phones, laptops, computers, RFID devices, navigation devices, radar (all devices using wireless communication such as LTE, 5G, Bluetooth, GPS, RFID etc.)	yes	3(3)(d)(e)(f) + DA (for scope and ER); 17 (conformity assessment)

	obsolete at the time when the horizontal legislation starts applying.								
Medical devices - Regulation (EU) 2017/745	out right exclusion of medical devices from the scope of the horizontal regulation due to more specific requirements set out in the medical devices regulation that are at least equivalent with the cybersecurity requirements in the intervention.	yes	yes	no	H1-like, B-like, D-like, F-like	Medical devices	High frequency ventilators, wearable automated external defibrillators, implantable pacemaker pulse-generator, coronary stents, cardiovascular catheters including guidewires and electrodes for electrophysiological diagnosis; Devices intended to remove undesirable substances out of the body, devices intended to separate cells by physical means, long term corrective contact	yes	52, Annexes IX - XI

							lenses, therapeutic devices intended to administer or exchange energy in a potentially hazardous way; Tracheostomy or tracheal tubes connected to a ventilator, short term corrective contact lenses, therapeutic devices intended to administer or exchange energy in a non-hazardous way, devices intended for recording X-Ray diagnostic images		
In vitro diagnostic medical devices - Regulation (EU) 2017/746	out right exclusion of medical devices from the scope of the horizontal regulation due to more specific requirements set out for in vitro diagnostic medical devices that are at least equivalent with the cybersecurity requirements of the intervention	yes	yes	no	B-like+D-like, H1-like	In vitro diagnostic medical devices	Reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, and accessories.	yes	48, Annexes IX - XI

Machinery Regulation – DRAFT COM(2021) 202	Complementarity, as MR covers cybersecurity with an impact on safety. The regulatory intervention would complement with requirements going beyond those having an impact on safety. Specific clarifications (provisions and recitals) could be considered to spell out the interplay between the two pieces of legislation, notably on aspects relating to safety (e.g. cross-referencing to application of Annex III relevant provision - e.g. 'protection against corruption')..	yes	yes	yes, as a rule (not for high-risk machinery)	Presumption of conformity of machinery when manufacturers apply harmonised standards; self-assessment by default option; third party assessment for high-risk machinery	Machinery products: (a) machinery;
						(b) interchangeable equipment;
						(c) safety components;
						(d) lifting accessories;
						(e) chains, ropes, slings and webbing;
						(f) removable mechanical transmission devices;
						(g) partly completed machinery;
						Additionally, as compared to the current MD, the definition of safety component has been also clarified to include non-physical components such as software. A list of exclusions is also provided as in the current Machinery Directive, with few adjustments
							All machinery embedding AI systems ensuring safety functions and (non-embedded) AI ensuring a safety function in machinery	yes	Annex III, 21, 22

						(some changes on vehicles to ensure nothing is left out) and further clarifications (mainly when such products are covered by other legislation, such as motor/vehicles, electrical equipment designed for use within certain voltage limits, etc.)			
Toy Safety - Directive 2009/48/EU	Complementarity to RED and hence RED Delegated Regulation	yes	yes (very limited)	yes	Presumption of conformity for toys applying harmonised standards, self-assessment as default. Third-party notification when there are no standards, or not applied or published with restriction or upon choice of manufacturer	Toys for Children (<14)	AI-powered Toy Robots (e.g. Sphero, Cozmo, Hello Barbie)	yes	Annex I, 19

Machinery – Directive 2006/42/EU	Directive to be replaced by Regulation (see above)	yes	yes (e.g. limited references to h/w and s/w in control systems)	yes	Presumption of conformity of machinery when manufacturers apply harmonised standards; self-assessment by default option. For high-risk machinery (listed in Annex IV) where no harmonised standards exist, (a) the EC type-examination procedure, plus the internal checks on the manufacture of machinery OR (b) the full quality assurance procedure. *Note: High-risk machinery – listed in Annex I + COM empowerment for DA to update the list (if it poses a risk to human health taking into account its design and intended purpose + some criteria to establish that).*	Machinery products (incl. software ensuring safety functions, including AI systems) - *'safety component' means a physical or digital component, including software, of machinery which serves to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endangers the safety of persons but which is not necessary in order for the machinery to function or may be substituted by normal components in order for the machinery to function.*	(a) machinery; (b) interchangeable equipment; (c) safety components; (d) lifting accessories; (e) chains, ropes and webbing; (f) removable mechanical transmission devices; (g) partly completed machinery; *A list of exclusions is also provided a (mainly when such products are covered by other legislation, such as motor/vehicles, electrical equipment designed for use within certain voltage limits, etc.)*	yes	3(3), 12, 13, Annex I, Annexes VIII - X

Transportable pressure equipment - Directive 2010/35/EU	No amendments necessary, the regulatory intervention to complement. Essential requirements refer to requirements under ADR, RID and (Agreements on the carriage of dangerous goods by resp. road, rail or waterway), which seem to contain requirements linked to safety, and no specific cybersecurity requirements.	yes	no	no	type approval, supervision of manufacture, periodic/intermediate inspections and exceptional checks, initial inspections and tests, reassessment of conformity	Transportable pressure equipment	All pressure receptacles, their valves and other accessories + tanks, battery vehicles/wagons, multiple-element gas containers (MEGCs), their valves and other accessories	yes	2(15), 4, 13
Motor vehicles and their trailers - Regulation (EU) 2018/858	Out right exclusion from the scope of the horizontal regulation due to more specific cybersecurity requirements where compliance with a specific UN regulation is required (*UN Regulation No 155 – Uniform provisions concerning the approval of vehicles with regards to*	yes	yes	no	different forms of type-approval	Motor vehicles and their trailers	Motor vehicles, trailers, systems, components, separate technical units, parts, equipment	no	

	cybersecurity and cybersecurity management system [2021/387])								
Recreational craft and personal watercraft - Directive 2013/53/EU	No amendments necessary, intervention will complement.	yes	no	for some	A, A1, B+C, B+D, B+E, B+F, G, H, Post construction Assessment (PCA)	Recreational craft, personal watercraft, propulsions engines	Motorboats, sailboats, personal watercraft, propulsion engines, kill switches, steering wheels, fuel tanks, port lights	yes	20, 21, 22 - this choice is not understandable. Relevant for what?
Simple Pressure Vessels - Directive 2014/29/EU	No amendments necessary, intervention to complement.	no	no	no	B+C-like, B+C1, B+C2	Simple Pressure Vessels		yes	13
Non-automatic Weighing Instruments - Directive 2014/31/EU	No amendments necessary, intervention to complement. Some of the general requirements refer to issues related to cybersecurity such as prevention of fraudulent use.	yes	yes	no	B+D, B+F, D1, F1, G	Non-automatic weighing instruments		yes	13

Lifts - Directive 2014/33/EU	Interplay with the intervention depends on decided interplay with Machinery Directive /Machinery Regulation. Essential requirements (relating to health and safety) refer to Machinery Directive (Annex I of the MD; The essential health and safety requirements of point 1.1.2 of Annex I to Directive 2006/42/EC apply in any event.)	yes	yes [*to the extent of the scope of the Lifts Directive dealing with health and safety of lifts and safety components for lifts*]	no	B+C2, B+D, B+E, G, H, H1	Lifts, safety components for lifts	Lifts intended for the transport of persons, goods and fitted with controls inside the carrier; Safety components for lifts components for lifts listed in Annex III, e.g. devices for locking landing doors, overspeed limitation devices, safety circuits containing electronic components	yes	15, 16 1(3) in case of more specific Union law 6(1) as regards building interface including aspects related smart building systems if relevant 4, 5, 7, 8 Annex I: preliminary remarks 1 to 3, essential health and safety requirements 1.1 and all those related to regulating, controlling and monitoring of safety of lifts where interconnected programmable/smart functions can be used (analysis to be carried out on case-by-case)
Marine Equipment - Directive 2014/90/EU	No amendments necessary, intervention to complement.	yes	no	no	B+D, B+E, B+F, G	Marine equipment		yes	15
Cableway installations - Regulation (EU) 2016/424	No amendments necessary, intervention to complement. No specific cybersecurity requirements; essential requirement related to safety.	yes	no	no	B+D, B+F, G, H1	Subsystems of cableway installations; Safety components	Drives and brakes, cable winding gear, cableway vehicles, monitor and safety devices; Components intended to be incorporated into a subsystem or cableway for the	yes	18(2)

							purpose of ensuring a safety function		
Gas appliances - Regulation (EU) 2016/426	No amendments necessary, intervention to complement, depending on the interpretation of the scope of the mandatory risk assessment (see above). No specific cybersecurity requirements; general safety requirements and requirements linked to materials used, design and construction.	yes	not through specific requirements but products must be safe and correctly performing when normally used as regards risks due to use of gas as fuel	no	B+C2, B+D, B+E, B+F, G	appliances burning gaseous fuels; Safety devices	Gas cookers, ovens, space heaters, instantaneous and storage water heaters, camping lanterns, blow lamps, greenhouse heater, coffee machines gas fires, convector heaters, catalytic heater, air heaters, radiant heaters, boiler including district heating, boiler bodies, heat pumps, humidifiers, co-generation appliances, fuel cells, steam boiler units, refrigerators, deep freezers, air-conditioning units, washing machines, drying cabinets, tumble dryers, dish washing machines, ironing machines, appliance governors/appliance pressure regulators, multifunctional controls, burner control systems, etc.	yes	14(2)

Pressure equipment - Directive 2014/68/EU	No amendments necessary, intervention to complement. No specific cybersecurity requirements; requirements linked to safety.	yes	no	Only for products with limited pressure hazard (category I under PED)	All except A1, C1, F1; A only for products classified under PED as category I	In fact Essential Safety Requirements relate to the products, the category of the equipment determines the stringency of the conformity assessment procedure	Stationary pressure equipment such as storage vessels, piping, heat exchangers, boilers, ... The applications include consumers products (fire extinguishers, pressure cookers) but the main applications are industrial process systems (chemical, pharmaceutical, power industry)	yes	14 Why only Art. 14?
ATEX (equipment and protective systems intended for use in potentially explosive atmospheres - Directive 2014/34/EU	No amendments necessary, complementary and compatible with the horizontal initiative. ATEX Directive contains the provision of Annex II.1.5.8 on Risks arising from software. It states that: 'In the design of software-controlled equipment, protective systems and safety devices, special account must be taken of the risks arising from faults in the programme'.	yes	yes (limited only to some risks from software)	for some	A (only for some products), B+C1, B+D, B+E, B+F, G	Equipment Group I; Equipment Group II; Protective systems, Components	Equipment used in all premises where a potentially explosive atmospheres may appear, such as: coal an mining industry, petrochemical industry, agriculture, etc.	yes	4, 13, Annex I - why this choice? Relevant to what?

Personal protective equipment - Regulation (EU) 2016/425	No amendments necessary, intervention to complement; no cybersecurity (or even digital) element	Yes, for smart garments only	no	for PPE category I only	A (only for category I products), B+C, B+C2, B+D	Equipment providing protection to the user against different types of risk:
						category I;
						category II;
						category III
							See Annex I of the PPE Regulation for PPE risk categories
							Category I PPE protect against low risks like superficial mechanical injury, atmospheric conditions that are not of an extreme nature, etc.
							Category II is all protective equipment (e.g. gloves, jackets, hats, glasses, masks, headphones) not covered under Category I or III
							Category III products are those who protect against at least one of the following risks:
							- substances and mixtures which are hazardous to health,
							- atmospheres with oxygen deficiency
							- harmful biological agent
							- ionizing radiation
							- high temperature environments (100°C)
							- low temperature environments (-50°C)
							- falling from a height;
							- electric shock and live working;
								yes	15(2), 19

							- drowning; - cuts by hand-held chainsaws; - high-pressure jets; - bullet wounds or knife stabs; - harmful noise.		
Drones - Regulation 2018/1139, Implementing Regulation (EU) 2019/947 and Delegated	intervention to complement or to consider Drones Regulation as lex specialis.	yes	yes (limited)	for some	A (only for some products and if harmonised standards applied), B+C, H	Drones (unmanned aircraft systems)		yes *(Delegated Regulation*)	Delegated Regulation (EU) 2019/945 – Art. 13 and Annex (parts 7, 8, 9)

Regulation (EU) 2019/945									
Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU	No amendments necessary, intervention to complement; no cybersecurity (or even digital) element	no	N/A	yes	A	Restriction of use of hazardous substances in electrical and electronic equipment (EEE)	Lists restricted substances for EEE	yes	7(b)
Electromagnetic Compatibility - Directive 2014/30/EU	No amendments necessary, angle; EMCD applies to all (non-radio) electrical equipment. It is more over true for computers wired connected (without Wi-Fi, bluetooth...) by for example "Ethernet cables RJ45".	yes	N/A	yes	A, B+C	Any apparatus or fixed installation [radio equipment are excepted – as RED applicable]	E.g. Apparatus: induction hobs, microwave ovens, washing machines, vacuum cleaners, power tools, LED lights, witching power supply, solar panels. E.g. fixed installations: TV screens and signage, wind turbines, air conditioning systems, etc.	yes	14, 15(2), Annexes II, III, IV

Low Voltage - Directive 2014/35/EU	No amendments necessary, intervention to complement; Does not have a digital dimension. Furthermore, there is no empowerment for a delegated act to update the list of specific requirements in Annex I.	yes	N/A	yes	A	Electronic and electrical equipment (non-radio) within certain voltage limits	Household and similar electrical appliances, rotating electrical machines, cables, power supply units, laser equipment, circuit breakers, control gears, switchgears, capacitors, fuses, luminaires and lamps, etc. ==> not exclusively household application, several also have industrial application	yes	15(2), Annex III, Annex IV
Pyrotechnic Articles - Directive 2013/29/EU	No amendments necessary, intervention to complement. Does not have a digital dimension.	no	N/A	no	B+C2, B+D, B+E, G, H	Pyrotechnic articles	Any article containing explosive substances or an explosive mixture of substances designed to produce heat, light, sound, gas or smoke or a combination of such effects through self-sustained exothermic chemical reactions; e.g. fireworks, theatrical pyrotechnic articles, ignition devices, etc	yes	17, Annex I, Annex II
Civil Explosives - Directive 2014/28/EU	Intervention could complement. DA/IA empowerment to update list of	no	N/A	no	B+C2, B+D, B+E, B+F, G	Explosives for civil uses (pyrotechnic articles covered by Directive	Projectiles, grenades, smoke, certain types of fireworks, signals, etc.	yes	20

	essential or specific requirements, cyber elements could be potentially added on this legal basis for the safety angle); (Art 46, 48)-linked to safety					2013/29/EU excluded)			
Noise emission in the environment by equipment for use outdoors - Directive 2000/14/EC	No amendments necessary, intervention to complement. There might be a digital dimension, but requirements under this Directive are limited only to noise emission requirements.	no (some of the equipment covered could have a digital dimension, but the directive's requirements are limited to noise emission)	N/A	yes	A-like, A2-like, G-like, H-like	Equipment for use outdoors. 57 equipment categories covered. 22 subject to noise limits and different conformity assessment procedures.	all machinery defined in Article 1(2) of Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery which is either self-propelled or can be moved and which, irrespective of the driving element(s), is intended to be used, according to its type, in the open air and which contributes to environmental noise exposure. E.g. tower cranes, motor hoes, hydraulic hammers, lawnmowers, piste caterpillars, etc.	No	14

Fertilisers – Regulation (EU) 2019/1009	No amendments necessary, intervention to complement.	no	N/A	for some	A (only for some products - depending on composition), A1, B+C, D1	Fertilising products	a substance, mixture, micro-organism or any other material, applied or intended to be applied on plants or their rhizosphere or on mushrooms or their mycosphere, or intended to constitute the rhizosphere or mycosphere, either on its own or mixed with another material, for the purpose of providing the plants or mushrooms with nutrient or improving their nutrition efficiency	yes	13, 15, Annex IV, Part I
Construction products - Regulation (EU) 305/2011	No amendments necessary, intervention to complement.	no	N/A	only self-assessment	Self-assessment as a rule (DoP). Production control and product testing; however, no correspondence with modules	Construction products	Any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works	yes	4, 6, 28(2), 60, Annex V

Table 29: Table illustrating the potential interplay between a horizontal regulatory intervention with existing product-related legislation

ANNEX 10: EU FUNDING PROGRAMMES

The table below provides a list of relevant headings in EU funding programmes. These headings show how EU funding programmes will support SMEs and public authorities in implementing the measures to be taken under a possible horizontal regulatory initiative.

Digital Europe WP 2021-2022 Source: https://ec.europa.eu/newsroom/repository/document/2021-45/C_2021_7913_1_EN_annexe_acte_autonome_cp_part1_v3_zCcOBWbBRKve4LP5Q1N6CHOVU_80908.pdf	
Topic	**Indicative Budget in m EUR**
European Cyber Shield	
EU Cybersecurity Resilience, Coordination and Cybersecurity Ranges	15
Uptake of innovative cybersecurity solutions in SMEs	32
Support to the health sector cybersecurity	10
Support to Implementation of relevant EU Legislation	
Deploying The Network Of National Coordination Centres With Member States (*Support through the Network of National Coordination Centres*)	27
Supporting the NIS Directive implementation and national cybersecurity strategies	20
Testing and certification capabilities	5
Total	109
Horizon Europe WP 2021-2022 Source: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-6-civil-security-for-society_horizon-2021-2022_en.pdf	
Topic	**Indicative Budget in m EUR**
Dynamic business continuity and recovery methodologies based on models and prediction for multi-level Cybersecurity	21.5
Improved security in open-source and open-specification hardware for connected devices	18
AI for cybersecurity reinforcement	11
Scalable privacy-preserving technologies for cross-border federated computation in Europe involving personal data	17
Secure and resilient digital infrastructures and interconnected systems	21.5
Hardware, software and supply chain security	18
Cybersecurity and disruptive technologies	11
Smart and quantifiable security assurance and certification shared across Europe	18
Total	**136**

Table 30: Relevant headings in EU funding programmes

Annex 11: The New Legislative Framework (NLF)

Many products placed on the EU market have CE marking (CE) affixed to them. This marking is the visible symbol showing that the manufacturer has taken all necessary measures to ensure that the product complies with the applicable safety legislation. It plays a crucial part in the New Legislative Framework for the EU internal market for goods, which entered into force at the beginning of 2010. The New Legislative Framework is a blueprint for designing product regulation at EU level. It provides for the appropriate control of testing laboratories and certification bodies, and more importantly sets out a Union policy on surveillance of products on the market and of effective controls of products from third countries.

European product legislation was revolutionised by the "New Approach" introduced in 1985. The 'old approach' reflected the traditional manner in which national authorities drew up technical legislation, going into great detail – usually motivated by a lack of confidence in the rigour of economic operators on issues of public health and safety. This New Approach departs from this traditional approach and has become a role model for Better Regulation. So-called New Approach legislation sets out the levels of protection that must be achieved and does not pre-judge the choice of technical solutions to achieve the levels. Today, the New Approach directives cover a large proportion of products marketed in the EU in more than 20 industrial sectors, including electro-technical products, machinery, radio/telecoms equipment, toys, medical devices, construction products and high-speed rail systems. Most products covered by this legislation have CE marking affixed to them, which is the visible symbol that indicates that a product complies with all the applicable safety legislation.

A detailed description of the New Legislative Framework can be found in the Commission's 'Blue Guide' on the implementation of EU products rules.[141]

1. About the CE marking

The CE marking is required for the placing of the market of products falling under specific product categories and indicates that such products meet EU safety, health or environmental requirements. It guarantees the free movement of safe products within the European market and is a key indicator of a product's compliance with EU legislation.

The CE marking is affixed by the manufacturer to its products. By placing CE marking on a product, the manufacturer declares the product's conformity with the applicable legal requirements valid in Europe. It is the sole responsibility of manufacturers to verify that the goods they are selling comply with all relevant legislations or – if necessary – have to have it examined by a notified conformity assessment body for that purpose.

Not all products sold in the EU need to bear CE marking. CE marking applies to more than 20 different product categories, ranging from electrical equipment to toys and from explosives to medical devices. Each product falls under one or more Directives, which determine the specific requirements that the product must meet in order to be CE-marked. Only the product categories subject to specific directives are required to be CE marked.

Wholesalers and retailers also bear some responsibility: they must verify that all the goods they distribute which require a CE marking are actually carrying one and that the necessary controls have been carried out.

[141] European Commission (2016): "The 'Blue Guide' on the implementation of EU products rules 2016", https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0726%2802%29.

In order to avoid non-conformity abuses, legal measures and economic sanctions have been established to deter the vast majority from doing so.

2. Six steps to obtain the CE marking

To comply with legal requirements, manufacturers have to follow six necessary steps in order to make their products ready for the market:

1. **Identify the directive(s) and harmonised standards applicable to the product:** The essential requirements products have to fulfil (e.g. safety) are harmonised at EU level and are set out in general terms in the Directives. Harmonised European standards are issued with reference to the applied directives and express in detailed technical terms the essential requirements.
2. **Verify the product-specific requirements:** It is up the manufacturers to ensure that their products comply with the essential requirements of the relevant EU legislation. Full compliance of a product to the harmonised standards gives to the product the "presumption of conformity" with the relevant essential requirements. The use of harmonised standards remains voluntary as manufacturers may decide to choose other ways to fulfil the essential requirements.
3. **Identify whether an independent conformity assessment is required from a notified body:** Each directive covering a particular product specifies whether an authorised third party (notified Body) must be involved in the conformity assessment procedure necessary for CE marking.
4. **Test the product and check its conformity to the EU legislation:** One part of the procedure is a risk assessment. By applying the relevant harmonised European standards, the manufacturer will be able to fulfil the essential legislative requirements of the directives.
5. **Draw up and keep available the required technical documentation:** The manufacturer has to establish the technical documentation required by the Directive(s) for the assessment of the product's conformity to the relevant requirements and a risk assessment. Together with the declaration of conformity, the technical documentation must be presented on request to the competent national authorities.
6. **Affixing the CE mark to your product and Declaration of Conformity:** The CE marking must be affixed by the manufacturer, according to its legal format visibly, legibly and indelibly to the product or its data plate. If a Notified Body was involved in the production control phase, its identification number must also be displayed.

3. Conformity assessment

Conformity assessment is the process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled. The legislator selects from the menu of conformity assessment procedures (laid down under Decision No 768/2008/EC) the most appropriate one(s) in order to address the specific needs of the concerned sector.

The following procedures are considered for policy options 3 and 4:

- **Internal production control ("self-assessment"):** The manufacturer himself ensures the conformity of the products to the legislative requirements.
- **Conformity assessment by a third party:** These third parties are laboratories, inspection and certification bodies which are known generally as conformity assessment bodies, or more formally as "Notified Bodies". Member States have the

responsibility to decide which of their conformity assessment bodies fulfil the necessary criteria to become notified since not all do. Accreditation is a formal system which provides an independent attestation of the competence, impartiality and integrity of conformity assessment bodies. The minimum criteria include competence, impartiality, integrity, etc. Notified bodies are private companies and operate in a competitive market.

4. **Market surveillance**

The enforcement of product safety legislation is an important task; not only to protect consumers and other users from unsafe products but also to ensure a level playing field for reputable businesses. In the EU market surveillance is the responsibility of the Member States, which establish market surveillance authorities for the different products covered by the 'New Legislative Framework. With the RAPEX system (see IP and Memo 10/130 on the 2009 Annual RAPEX Report) the European Union has an effective and efficient system in place to share information about dangerous products found on the European market.

3. **Policy options 3 and 4 and the New Legislative Framework**

Under policy options 3 and 4, the Commission would propose a regulation laying down cybersecurity requirements for products with digital elements. The intervention would be based on the New Legislative Framework's (NLF) blueprint for product regulation. In line with the NLF, it would lay down objective oriented cybersecurity requirements, leaving the technical details to European harmonised standards. It would also require manufacturers to carry out a conformity assessment, with self-assessment for the vast majority of products and third-party assessment by notified bodies for a small number of critical products. Member States would be required to designate notified bodies to carry out the procedures for conformity when a third party is required. They would also need to establish market surveillance authorities to prevent the making available on the market and use of non-compliant products.

Due to the nature of products with digital elements, policy options 3 and 4 will slightly adjust the "traditional" NLF approach in a number of ways:

- In the past, NLF legislation would lay down safety, health or environmental requirements. Policy options 3 and 4 will **introduce cybersecurity requirements**, which have so far not played any major role in NLF legislation (with the exception of the Radio Equipment Directive together with a recently adopted delegated regulation and a few safety-focused product regulation that partially take cybersecurity into account, such as the Toy Safety Directive).
- Most NLF legislation lays down requirements for tangible goods (such as toys or machinery). Policy options 3 and 4 would **introduce requirements for software as a non-tangible good**. While policy option 3 would only cover software embedded in hardware devices, policy option 4 would cover all software. The Radio Equipment Directive together with a recently adopted Delegated Regulation are also covering embedded software. In addition, the Medical Devices Regulation also covers software products.
- Unlike traditional NLF legislation, policy options 3 and 4 would not only lay down requirements for the placing on the market of products with digital elements but **cover the entire life cycle of such products**. Manufacturers will therefore be required to ensure that products are kept secure by issuing security updates for vulnerabilities discovered in their products. The whole life cycle approach is necessary, as it is nearly impossible to develop products with digital elements that do not have any vulnerabilities at all.

ANNEX 12: ILLUSTRATION OF TWO-LEVEL RISK APPROACH TO CONFORMITY ASSESSMENT IN POLICY OPTION 4

Level of risk category	**Criteria of determining the risk level of the product**	**Type of product**	**Conformity assessment**	**European certification scheme on the basis of the Cybersecurity Act**
By default (for the vast majority of the products in the scope)	By default	All products with digital elements but those qualified as critical	Self-assessment (flexible approach – businesses can still choose third party)	Presumption of compliance with the horizontal requirements for the relevant category of products **Mandatory certification based on an available EU cybersecurity certification scheme for products could be considered, based on an empowerment for delegated act. The EU certification scheme would follow the relevant procedures of the Cybersecurity Act.*
Critical (narrow market share)	Functionality/ security-critical functions	Critical software, e.g. operating systems or firewalls	Third-party assessment	
	Intended or reasonably foreseeable use	Industrial control and automation systems used by entities		

Table 31: Illustration of a risk approach to conformity assessment in policy option 4

ANNEX 13: REGULATORY GAP ANALYSIS

Currently there are **no specific cybersecurity requirements comprehensively and systematically applicable to all products with digital elements**, hardware or software, accessing the internal market. Cybersecurity of software (embedded in hardware and upload-able or of generic use, i.e. standalone[142]) in particular, of key importance for cybersecurity policies, is the least regulated even at the level of sector- or product-specific legislation with limited scope.

In order to effectively ensure the security of products as per the problems identified, **comprehensive and systematic cybersecurity requirements** applicable to all products with digital elements, should entail as key minimum elements, (see *section 5.2)* that: (i) **cybersecurity is factored in the design and development** of the products with digital elements and that due diligence is exercised by manufacturers on security aspects when designing and developing their products, (ii) **transparency** is ensured on cybersecurity aspects that need to be made known to customers and (iii) **security support (updates and handling of vulnerabilities)** are provided after the placement on the market.

More specifically, such security requirements would include:

- aspects relating to the **properties of the products** such as: security by default; protection from unauthorised access; confidentiality and integrity of data, commands and programs; capability to perform or support integrity checks; availability of components against degradation and distributed denial of service attacks; protection of the exposed attack surfaces; enable adequate security updates.
- security **support** (i.e. **vulnerability handling, security updates, patching**) for the **whole life cycle (i.e. after the placement on the market)**, such as requirements to: identify dependencies and vulnerabilities, including composition of software used and supply chain-related information; have no known-vulnerabilities and address vulnerabilities without delay; test the security of the product with digital elements; have in place a process to quickly become aware of newly emerging vulnerabilities; ensure mechanisms allowing the secure updating; ensure that patches are delivered with advisory messages; have coordinated vulnerability disclosure policies.
- provision of **information and instructions** such as those concerning: contact information for reporting vulnerabilities; intended use, including the security environment foreseen; end of life of the product; security properties of the product; type of support offered and for how long; instructions on secure use and secure removal of data.

The following legislative gaps can be highlighted in both (A) general cybersecurity-related legislation and (B) product-related legislation:

A) **General cybersecurity-related legislation,** (including product-related) which is applicable across-sectors and/or across-products

- **The "NIS Directive"** or Directive concerning measures for a high common level of security of network and information systems across the Union (')[143], recently reviewed through the NIS2 Directive[144] imposes on entities operating in key sectors

[142] i.e. software that can be purchased by end users separately, such as operating systems; mobile apps; desktop applications; video games.

[143] Directive (EU) 2016/1148 (NIS Directive)

[144] 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. The NIS2 Directive reached a provisional political agreement and is expected to be formally adopted by autumn 2022

obligations of organisational and risk management nature, including due diligence supply chain security obligations.

- <u>*Limitations:*</u> These obligations do not entail requirements for the design or development or security support of products and can only have indirect effects in that regard.

- **General Data Protection Regulation (GDPR)[145]** lays down rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data.
  - <u>*Limitations:*</u> It does not regulate the cybersecurity of products.
- The **Cybersecurity Act[146]** sets a framework for the development, at EU level, of voluntary certification schemes for specific ICT products, services and processes.
  - <u>*Limitations:*</u> While covering a similarly broad scope when it comes to products with digital elements as policy option 4, the Cybersecurity Act does not establish any mandatory cybersecurity requirements or legal obligations for placing products with digital elements on the market. Even if an EU certification scheme exists (currently 3 schemes are being developed)-, manufacturers do not have a legal obligation to seek certification for those products. A separate appropriate legislative framework would be required for such an end.

B) <u>Product legislation</u>

(i). General product legislation

- **General Product Safety framework**, i.e. the General Product Safety Directive (GPSD)[147], undergoing review through a General Product Safety Regulation (GPSR)[148] currently in the co-decision process[149]. It establishes requirements to ensure the safety of consumer products (both covered and not by harmonised legislation). The GPSR proposal states that cybersecurity risks that have an impact on the safety of consumers are covered by the concept of safety. The GSPR proposal clarifies[150] also that specific cybersecurity risks affecting the safety of consumers can be dealt with by sectorial [i.e. specific] legislation, GSPR acting as a **safety net** in case of gaps of such legislation.
  - <u>*Limitations:*</u> The generic requirement to factor in cybersecurity risks from the safety angle does not ensure *de jure* or *de facto* cybersecurity by design and by default of all these products throughout the lifecycle or any security support. Even if some cybersecurity attacks could present a safety risk, this is far from comprehensive in terms of possible cybersecurity risks.
- **Product Liability framework**, i.e. the Product Liability Directive[151] currently under review, with a proposal due in autumn 2022. The product liability framework

[145] Regulation 2016/679/EU.

[146] Regulation (EU) 2019/881

[147] Directive 2001/95/EC.

[148] On 30 June 2021, the European Commission adopted a proposal for a new general product safety regulation, with a view of improving the safety of non-food consumer products on the internal market. Announced in the new consumer agenda strategy, the proposal aims to replace the current General Product Safety Directive

[149] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council of 30 June 2021, COM(2021) 346 final.

[150] Recital 22 of the GPSR proposal.

[151] Directive 85/374/EEC.

intervenes *ex post* by setting out liability rules for defective products so that consumers can claim compensation when a damage has been caused by defective products. More specifically, it establishes the right of injured persons to be compensated for damages caused by the defectiveness of a product. It establishes the principle that the manufacturer of a product is liable for damages caused by a defect in their product irrespective of fault ('strict liability'). The planned review of the product liability framework aims to update the definition of products, to also include software and to introduce, among others, liability for situations when damages are triggered by vulnerabilities after the placement of the product on the market, having regard to all circumstances.

- *Limitations*: It does not set product requirements, let alone cybersecurity requirements for products. If a defective product with digital elements was not compliant with established cybersecurity requirements, this would be relevant in the damages case and trigger the liability of the manufacturer in question. Manufacturers cannot be held liable for how the product will be used, but they would have to comply with requirements that ensure security of the product regarding its design and development, make available information to the users on security features and functions and make available security support and relevant information in relation to that. The liability of an economic operator may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person [including, for example, rejecting a software security update] or any person for whom the injured person is responsible. The product liability legislation is therefore **complementary and not substitutable to a legislation establishing product requirements**.

(ii).Sector or product-specific- New Legislative Framework (NLF) legislation and remaining 'old approach' legislation

- The NLF framework typically sets essential requirements as a condition for the placement of certain products on the internal market. These requirements are objective-oriented, followed at a later stage by harmonised standards. It also typically provides for conformity assessment, which is the process conducted by the manufacturer to demonstrate whether specified requirements relating to a product have been fulfilled and provides for EU market surveillance under the responsibility of the Member States.

- In the context of EU sector-specific safety legislation, so-called old and new approaches are traditionally distinguished. The 'Old Approach' refers to the very initial phase of EU regulation on products, whose main feature was the inclusion of detailed technical requirements in the body of the legislation. Certain sectors such as transport are still being regulated this way.

- Many of these sectors cover products that are not connected, and for which the cybersecurity angle is not applicable. For those products which are digital, the current product-related legislation covers only certain aspects linked to the cybersecurity, if any, and, where applicable, only embedded software. Duty of care for whole lifecycle after the placement on the market, a key aspect for cybersecurity of products, is typically not covered by this type of legislation.

- A regulation of security of all software, including non-embedded, is a crucial missing aspect of the existing product legislation. Vulnerabilities in software are omnipresent and have cascading effects cross-sectors and borders. The examples of cyberattacks affecting software and the whole supply chain are abundant. Examples include the

Pegasus spyware, which exploits vulnerabilities in mobile phones and has been used by governments to spy on critics and opponents, as well as against prominent political leaders in Europe; the Kaseya VSA supply chain attack, which used Kaseya's network administration software to attack over 1 000 companies, forcing a supermarket chain to close all its 500 shops across Sweden.

- As regards the overall interplay between NLF and 'old approach' legislation and any envisaged horizontal legislation establishing cybersecurity requirements for all products with digital elements, mention should be made that these would be complementary. The only potential outright exclusions (or *lex specialis* derogations) from the scope of a cybersecurity horizontal regulation would concern products (medical devices, cars) for which cybersecurity is regulated comprehensively in specific legislation on all key aspects (i.e. security in the design and properties of the product, whole life cycle, transparency and information). Even for those, cybersecurity requirements established by the horizontal regulation for standalone software, also upload-able on such products, would be complementary. A horizontal cybersecurity regulation on products with digital elements would not change the way products are placed on the internal market as per settled NLF, nor would it change the overall NLF governance setting (e.g. aspects such as market surveillance governance).

- The following product-specific pieces of legislation need particular attention because they are the only ones that cover cybersecurity aspects in a more detailed way :

a) **Radio Equipment Directive (RED)[152] and notably its Delegated Regulation[153]** establishes three essential security-related requirements for inter-connected radio equipment (i.e. wireless products): (i) ensure network protection; (ii) ensure safeguards for the protection of personal data and privacy, (iii) ensure protection from fraud.

   - *Limitations***:** cover **only wireless products** (hardware and their embedded software). It does not cover wired-only connect products, nor non-radio components (e.g. processors). It **does not cover standalone (non-embedded) software**. Furthermore, the requirements are **very generic, not providing key specific cybersecurity requirements** that would guarantee security by design and default (e.g. no requirements are provided addressing cybersecurity risks to availability, integrity, confidentiality; vulnerability handling; transparency and recording of composition of products an supply chain, obligations for specific security-related information to users, etc.) **or obligations regarding security support for whole life cycle, i.e. after the placement on the market**. *See also Annex 7 for a detailed comparison between the RED delegated act scope and requirements and those envisaged for a comprehensive horizontal cybersecurity regulation.*

b) **Machinery Directive[154] and proposal for a Machinery Regulation** proposed Regulation looks covers requirements and risks relating to and impacts on **safety**. It covers a certain category risks related to new digital technologies provoked by malicious third parties that have an impact on the safety of machinery products. It

[152] Directive 2014/53/EU.

[153] C(2021) 7672 final supplementing RED, with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of RED.

[154] Directive 2006/42/EC.

does not preclude the application to machinery products of other Union legislation specifically addressing cybersecurity aspects.

- _Limitations:_ cybersecurity is only covered from a narrower angle, safety-related for a very specific category of machinery products/components. It does not cover non-embedded software in its scope, nor requirements of duty of care for whole life cycle.

c) **Medical Devices Regulation (MDR)[155] as well as the In Vitro Diagnostic Medical Devices Regulation[156]** contain requirements regarding devices, including on software and general obligations on manufacturers, covering the whole life cycle of products, as well as conformity assessment procedures.

- _Limitations:_ the **scope is very narrow** limited to specific medical devices[157]. In relation to such specific legislation and in particular the specificity of cybersecurity requirements that cover key aspects, a potential comprehensive horizontal regulation setting out cybersecurity requirements could consider out rightly excluding such category of products from application.

d) **Regulation on motor vehicles[158] and Delegated Regulation**[159] requires vehicles to be protected against cyber-attacks. The Regulation empowers the Commission to develop detailed implementing rules. The Delegated Regulation introduces certain **cybersecurity requirements, including on software updates** and whole life cycle aspects, requiring compliance with specific UN regulations on technical specifications and cybersecurity[160] and providing for specific conformity assessment procedures.

- _Limitations:_ the scope is **limited to vehicles**. In relation to such specific legislation, given the specificity of cybersecurity requirements that cover key aspects, a potential comprehensive horizontal regulation setting out cybersecurity requirements could consider **out rightly excluding** such category of products from application.

e) **Artificial Intelligence (AI) Act proposal** establishes, among others, requirements for high-risk AI systems. More specifically, the proposal requires high-risk AI systems to be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and **cybersecurity**, and perform consistently in those respects throughout their lifecycle. A risk management system is also required throughout their **entire lifecycle**, as well as regular systematic updating.

- _Limitations:_ the **scope is very limited, i.e. high-risk AI systems** explicitly listed in the Act. The cybersecurity-related requirements are **generic**. Such legislation could be complementary to a comprehensive horizontal regulation introducing more specific cybersecurity requirements. Compliance with the latter could imply

[155] Regulation (EU) 2017/745.

[156] Regulation (EU) 2017/746.

[157] "For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation", Regulation (EU)2017/745, Annex I, Chapter II, REQUIREMENTS REGARDING DESIGN AND MANUFACTURE.

[158] Regulation (EU) 2019/2144, https://eur-lex.europa.eu/eli/reg/2019/2144/oj.

[159] Delegated Regulation (EU) 2022/545 supplementing Regulation 2019/2144; https://eur-lex.europa.eu/eli/reg_del/2022/545

[160] UN Regulation No 155 – Uniform provisions concerning the approval of vehicles with regards to cybersecurity and cybersecurity management system [2021/387].

compliance with the high-level cybersecurity requirements of the former. A specific legal act is currently in preparation at Commission level aiming to harmonise certain national non-contractual civil liability rules, so as to ensure that injured persons claiming compensation for harm caused by AI system enjoy the same level of protection as injured persons claiming compensation for harm caused without the involvement of an AI system. These would therefore strengthen the leverage of the AI Act requirements, and potentially also of any more specific horizontal cybersecurity requirements.

EU legislation (in force, in adoption process or in preparation)	***How are cybersecurity-relevant aspects covered***	***What is missing?***
Horizontal/general EU legislation not product-relevant		
NIS Directive[161] (and upcoming NIS2)	*Covers measures for a high common cybersecurity level across the Union to increase the level of resilience of entities in a number of sectors or providing certain services considered key ('critical' aka 'essential' and/or 'important') across the Union.*	*The NIS Directive does not impose cybersecurity requirements on products..*
General Data Protection Regulation (GDPR)[162]	*Its scope is limited to the general protection of personal data.*	*It does not regulate cybersecurity of products and does not provide an adequate legal basis for this.*
Horizontal regulatory framework on products		
***Cybersecurity Act**[163]*	*Introduces a framework to set certification mechanism for specific ICT products, services and processes.*	*There are currently not yet any EU cybersecurity certification scheme having been developed under the Cyber security Act (3 currently under development). Once in place, manufacturers will not have a legal obligation to seek certification for their products. This framework, while it establishes cybersecurity objectives that can be (and in fact are to be) integrated in horizontal cybersecurity requirements for products with digital elements, does not establish any cybersecurity requirements or legal*

[161] Directive (EU) 2016/1148

[162] Regulation 2016/679/EU

[163] Regulation (EU) 2019/881

EU legislation (in force, in adoption process or in preparation)	***How are cybersecurity-relevant aspects covered***	***What is missing?***
		obligations for placing products with digital elements on the market. A separate appropriate legislative framework would be required for such an end.
General Products Safety Directive (GPSD)[164] undergoing review through a General Product Safety Regulation (GPSR)[165] currently in the co-decision process	*Its main purpose is to address product safety. In the GPSR proposal, cybersecurity risks that have an impact on the safety of consumers are covered by the concept of safety (i.e. appropriate cybersecurity features necessary to protect the product against external influences, including malicious third parties, when such an influence might have an impact on the safety of the product).*	*GPSR does not establish specific cybersecurity requirements for products.* *Even if cybersecurity attacks could present a safety risk, the focus of the GPSR would remain the safety in a more narrow sense.* *Compliance with specific horizontal cybersecurity requirements would entail compliance with the cybersecurity risk angle required for safety under GSPR, but not vice-versa. GSPR requirements are far insufficient to ensure security by design and by default of products.*
Directive on liability for defective products (the Product Liability Directive)[166] and upcoming review	*It governs the liability of the manufacturers for damage caused by the defectiveness of the product.* *The planned review of the product liability framework aims to update the definition of products in line with other general product legislation, such as the product safety framework, to also include software and to introduce, among others, liability for situations when damages are triggered by lack of security updates which occurs after the placement of the product on the market, derogating from the*	*It does not set product requirements, let alone cybersecurity requirements for products. Instead, it sets out liability rules for defective products so that consumers can claim compensation for damage caused by defective products. These can indeed have effects on the manufacturers' designing and development of products.* *Such a legislation is complementary and not substitutable to a legislation*

[164] Directive 2001/95/EC.

[165] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council of 30 June 2021, COM(2021) 346 final.

[166] Directive 85/374/EEC

EU legislation (in force, in adoption process or in preparation)	***How are cybersecurity-relevant aspects covered***	***What is missing?***
	general rule on product liability that considers only defectiveness present at the time when the product was placed on the market. *With the planned review, vulnerabilities in a product could be classified as a defect for which the manufacturer would have the obligation to take appropriate cybersecurity measures during the design, production.*	*establishing product requirements.*
Union harmonisation legislation based on the New Legislative Framework (NLF)[167]		
Radio Equipment Directive (RED)[168] ***and relevant Delegated Regulation***[169]	*RED governs the safety aspects of wireless connected products, entails the possibility for the Commission to impose security requirements on the manufacturer linked to the protection of personal data and privacy by means of delegated acts*[170]*.* *The relevant delegated act establishes the following three essential security-related requirements for inter-connected radio equipment (i.e. wireless products): (i) ensure network protection; (ii) ensure safeguards for the protection of personal data and privacy, (iii) ensure protection from fraud.*	*The security requirements cover only wireless products (hardware and their embedded software).* *They do not cover standalone (non-embedded) software.* *Furthermore, they are very generic, not providing key specific cybersecurity requirements that would guarantee security by design and default (e.g. no requirements are provided addressing cybersecurity risks to availability, integrity, confidentiality; vulnerability handling; transparency and recording of composition of products an supply chain, obligations for specific security-related information to users, etc) or obligations regarding security support for whole life cycle, i.e. after the placement on the market.*

[167] Regulation (EC) 765/2008 and Decision No 768/2008/EC

[168] Directive 2014/53/EU

[169] C(2021) 7672 final supplementing RED, with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of RED

[170] See Article 3(3)(e)

EU legislation (in force, in adoption process or in preparation)	***How are cybersecurity-relevant aspects covered***	***What is missing?***
Machinery Directive[171] ***and proposal for a Machinery Regulation***[172]	*The proposed Regulation provides that manufacturers shall be required to adopt proportionate measures which are limited to the protection of the safety of the machinery product. This does not preclude the application to machinery products of other Union legislation specifically addressing cybersecurity aspects.* *The proposed Regulation makes the link with the future cybersecurity schemes pursuant to the Cybersecurity Act for the purpose of demonstrating compliance with the future regulation on machinery products. In particular, in view of addressing the risks stemming from malicious third party actions that have an impact on the safety of machinery products, the proposed Regulation includes essential health and safety requirements for which a presumption of conformity may be given to the appropriate extent by a certificate or statement of conformity issued under a relevant cybersecurity scheme adopted pursuant to the Cybersecurity Act.*	*The proposed Regulation only covers a certain category of risks related to new digital technologies provoked by malicious third parties that have an impact on the safety of machinery products.* *It does not cover duty of care for whole lifecycle, nor standalone software*
Medical Devices Regulation (MDR)[173] *and the* ***In Vitro Diagnostic Medical Devices Regulation***[174]	*It provides that for devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life*	*The scope is limited to specific medical devices*[175]*. It covers, supported by detailed guidelines, comprehensive cybersecurity requirements, including software (as well as some types of non-*

[171] Directive 2006/42/EC.

[172] COM/2021/202 final.

[173] Regulation (EU) 2017/745.

[174] Regulation (EU) 2017/746.

[175] "For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation", Regulation (EU)2017/745, Annex I, Chapter II, REQUIREMENTS REGARDING DESIGN AND MANUFACTURE.

EU legislation (in force, in adoption process or in preparation)	***How are cybersecurity-relevant aspects covered***	***What is missing?***
	cycle, risk management, including information security, verification and validation. *Detailed guidelines on cybersecurity measures are in place, covering specific cybersecurity requirements, including duty of care throughout whole life cycle.*	*embedded software) and duty of care for whole life cycle.* *A potential horizontal regulation could consider exempting such category of products from application (similar to a lex specialis principle).*
*Other product-specific **NLF legislation** (see also Annex 9 of the draft IA report)*	*General safety-related requirements.*	*Only certain generic safety requirements are applicable; no specific cybersecurity requirements.* *No provisions on duty of care for whole life cycle.* *Standalone software not covered.*
Other product-specific legislation or legislative initiatives		
***Regulation on motor vehicles**[176] **and Delegated Regulation** supplementing Regulation 2019/2144[177]*	*Cybersecurity is a precondition for consumer trust in **automated/connected vehicles**. Regulation (EU) 2144/2019 requires notably vehicles to be protected against cyber-attacks. The Regulation empowers the Commission to develop detailed implementing rules.* *The Delegated Regulation introduces certain cybersecurity requirements, including on software updates, requiring compliance with specific UN regulations on technical specifications and cybersecurity[178] and providing for specific conformity assessment procedures.* *The car manufacturers are required to carry out a cybersecurity risk analysis and to put in place robust car design*	*The scope is limited to a category of products (connected vehicles), but the cybersecurity requirements are comprehensive.* *It does not cover cybersecurity requirements for standalone (non-embedded) software.* *A potential horizontal regulation could consider exempting vehicles as regulated by this framework from application (similar to a lex specialis principle).*

[176] Regulation (EU) 2019/2144, https://eur-lex.europa.eu/eli/reg/2019/2144/oj.

[177] Delegated Regulation (EU) 2022/545; https://eur-lex.europa.eu/eli/reg_del/2022/545

[178] UN Regulation No 155 – Uniform provisions concerning the approval of vehicles with regards to cybersecurity and cybersecurity management system [2021/387].

EU legislation (in force, in adoption process or in preparation)	***How are cybersecurity-relevant aspects covered***	***What is missing?***
	measures to avoid or to mitigate these risks. *The Approval authority will verify the compliance of the vehicle by means of document checks and testing. Furthermore, in order to obtain a type approval, manufacturers will have to put in place a Cybersecurity Security Management System which will be certified by the vehicle approval authority. The Cybersecurity Security Management System is to ensure that the manufacturer has the effective internal processes in place to avoid cyberattacks during the whole lifetime of the vehicle (from the design to the end of life of a vehicle) to ensure monitoring of vulnerabilities of and cyber-attacks against its vehicles and to keep its risk assessment up to date.*	
Proposal for an ***Artificial Intelligence (AI) Act***[179] ***and upcoming AI liability rules***	*High-risk AI systems are required to be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle. They are also required to establish, implement, document and maintain a risk management system throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating A risk-based approach is ensured in this regard (i.e. technical solutions aimed at ensuring cybersecurity must be appropriate to the relevant circumstances and the risks).*	*The scope is limited only to a certain type of products (high risk AI system).* *The cybersecurity requirements for the high-risk AI systems are generic and not comprehensive.*

[179] COM(2021)206

EU legislation (in force, in adoption process or in preparation)	***How are cybersecurity-relevant aspects covered***	***What is missing?***
	A specific piece of legislation is currently in preparation regarding specific liability aspects for AI systems. In particular, it aims to lay down rules on the burden of proof in the case of non-contractual fault-based civil law claims brought before national courts for damages caused by the output of an AI system or the failure of such a system to produce an output and on the disclosure of information to be documented or logged pursuant to [the AI Act], to enable a claimant to substantiate a claim for damages. This would concern all relevant provisions of the AI Act, including the cybersecurity obligations.	

Table 32: Overview of EU legislation relevant for cybersecurity

ANNEX 14: STANDARDS RELATED TO PRODUCTS WITH DIGITAL ELEMENTS

Standards are technical means or specifications that are adopted by a recognised standardisation body. The key benefit of a standard is to build a common language and hence to ensure interoperability of products and services. In the EU, standards are voluntary and are developed by the industry and/or experts in the relevant field, either at their own initiative or at the request of a legislator.

In the case of European standardisation (EU Regulation 1025/2012), a harmonised European standard is a European standard developed at the request of the Commission by one of the European standardisation organisations (ESOs), in view of applying Union harmonisation legislation. Harmonised standards can be specific on how to implement the legislation, unlike essential requirements included in Union harmonisation legislation that are objective-oriented and technology-neutral.

While there is a variety of international standards concerning several aspects of product cybersecurity (consumer IoT, assurance of security throughout lifecycle or vulnerability handling, access control, etc.), no piece of EU legislation requires currently comprehensive cybersecurity requirements for all products with digital elements, and hence no harmonised European standards for products with digital elements across sectors.

As in all product-specific legislation of the NLF type, a horizontal regulation setting out cybersecurity requirements for products with digital elements marketed in the Union would also be followed by a standardisation request. The Commission typically sends a request to European standardisation bodies to set out harmonised standards laying down the technical means through which the requirements set may be met.[180] Typically the standards start being developed in the transition period provided for by the regulation in question, which could be 2 years for application to start after the entry into force. This ensures that by the time of the application of the new rules, harmonised European standards are already in place *(see also section 5.2. and notably the presentation of options 3 and 4).* The harmonised standards can be developed taking account and building on existing European and international standards.

The adoption of harmonised European standards provides a key incentive for manufacturers to follow these standards and provides legal certainty to manufacturers, especially for SMEs. Even if European and international standards exist, it can be costly for businesses to identify relevant standards to meet adequate security requirements. Contractual or public procurement obligations or indirect effects stemming from supply chain security obligations can provide certain incentives for compliance with existing standards. However, without a common European understanding on which standards meet adequate security requirements, there is a risk of market fragmentation. A common understanding on standards can be defined through voluntary measures, such as public procurement guidelines or European certification. However, such voluntary measures would not provide sufficent leverage to systematically integrate security in all products with digital elements.

Considering the level of connectivity and inter-dependence of products with digital elements, a scattered approach relying on voluntary application of standards and indirect effects of other obligations or self-regulation would not effectively address the identified problems of low level of cybersecurity of products with digital elements in the internal market, nor the insufficient understanding among users of the security of products.

[180] REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on European standardisation.

The table below presents an overview of existing standards and guidelines that touch upon cybersecurity of products with digital elements.

Standard	***Scope***
BSA	*Framework for Secure Software*[181]
ETSI EN 303 645	*Cyber Security for Consumer IoT: Baseline Requirements*[182]
ETSI TR 103 621	*Guide to Cyber Security for Consumer Internet of Things*[183]
ETSI TS 103 701	*Technical specification: Cyber Security Assessment for Consumer IoT*[184]
GSMA	*GSMA IoT Security Guidelines*[185]
GSMA	*IoT Security Guidelines for Endpoint Systems*[186]
ISA/IEC 62443 series	*Series of standards for Industrial Automation and Control System (IACS)*
IEC 62443 4-1	*Secure Product Development Lifecycle Requirements*[187]
IEC 62443 4-2	*Technical security requirements for IACS components*[188]
	Common Criteria[189]
ISO/IEC 5055	*Automated Source Code Quality Measures*[190]
ISO/IEC 27400:2022	*Cybersecurity - IoT Security and Privacy Guidelines*[191]
ISO/IEC 27034 series	*Information technology – Security techniques – Application Security*[192]
ISO/IEC 29147	*Information technology – Security techniques – Vulnerability disclosure*[193]
ISO/IEC 30111	*Information technology – Security techniques – Vulnerability handling processes*[194]
NIST	*Recommended Criteria for Cybersecurity Labelling for Consumer Internet of Things (IoT) Products*

[181] https://www.bsa.org/reports/updated-bsa-framework-for-secure-software
[182] https://www.etsi.org/deliver/etsi_en/303600_303699/303645/02.01.01_60/en_303645v020101p.pdf
[183] https://www.etsi.org/deliver/etsi_tr/103600_103699/103621/01.01.01_60/tr_103621v010101p.pdf
[184] https://www.etsi.org/deliver/etsi_ts/103700_103799/103701/01.01.01_60/ts_103701v010101p.pdf
[185] https://www.gsma.com/iot/resources/gsma-iot-security-guidelines-complete-document-set/
[186] https://www.gsma.com/iot/wp-content/uploads/2016/02/CLP.13-v1.0.pdf
[187] https://webstore.iec.ch/preview/info_iec62443-4-1%7Bed1.0%7Den.pdf
[188] https://webstore.iec.ch/preview/info_iec62443-4-2%7Bed1.0%7Db.pdf
[189] https://www.commoncriteriaportal.org/
[190] https://www.iso.org/standard/80623.html
[191] https://www.iso.org/standard/44373.html
[192] https://www.iso.org/standard/44378.html
[193] https://www.iso.org/standard/72311.html
[194] https://www.iso.org/standard/69725.html

NIST SP 800-213	*IoT Device Cybersecurity Guidance for the Federal Government: Establishing IoT Device Cybersecurity Requirements*[195]
NIST SP 800-218	*Secure Software Development Framework (SSDF)*[196]
NISTIR 8259	*Foundational Cybersecurity Activities for IoT Device Manufacturers*[197]
NISTIR 8259A	*IoT Device Cybersecurity Capability Core Baseline*[198]
OWASP ISVS	*IoT Security Verification Standard*[199]
OWASP ASVS	*Application Security Verification Standard*[200]
OWASP SCVS	*Software Component Verification Standard*[201]
SAFECode	*Fundamental Practices for Secure Software Development*[202]

Table 33: Notable examples of relevant international standards, widely used industry best practices and guidelines

[195] https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.02042022-2.pdf
[196] https://csrc.nist.gov/publications/detail/sp/800-218/final
[197] https://www.nist.gov/publications/foundational-cybersecurity-activities-iot-device-manufacturers
[198] https://www.nist.gov/publications/iot-device-cybersecurity-capability-core-baseline
[199] https://owasp.org/www-project-iot-security-verification-standard/
[200] https://owasp.org/www-project-application-security-verification-standard/
[201] https://owasp.org/www-project-software-component-verification-standard/
[202] https://safecode.org/uncategorized/fundamental-practices-secure-software-development/

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PART 3/3

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020

{COM(2022) 454 final} - {SEC(2022) 321 final} - {SWD(2022) 283 final}

Subsidiarity Grid

Proposal for a Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements (Cyber Resilience Act) and amending Regulation (EU) 2019/1020

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

The legal basis for this proposal is Article 114 of the Treaty of the Functioning of the European Union, which provides for the adoption of measures to ensure the establishing and functioning of the internal market. The purpose of the proposal is to harmonise cybersecurity requirements for products with digital elements in all Member States and to remove obstacles to the free movement of goods.

Article 114 TFEU may be used as a legal basis to prevent the occurrence of these obstacles resulting from diverging national laws and approaches on how to address the legal uncertainties and gaps in the existing legal frameworks.[1] Furthermore, the Court of Justice has recognised that applying heterogeneous technical requirements could be valid grounds to trigger Article 114 TFEU.[2]

The current EU legislative framework applicable to digital products is based on Article 114, and comprises several pieces of legislation, including on specific products and safety-related aspects or general legislation on product liability. However, it covers only certain aspects linked to the cybersecurity of tangible digital products and, as applicable, software embedded in these products. At national level, Member States are starting to take national measures requiring vendors of digital products to enhance their cybersecurity. At the same time, the cybersecurity of digital products has a particularly strong cross-border dimension, as products manufactured in one country are often used by organisations and consumers across the entire internal market. Incidents that initially concern a single entity or Member State often spread within minutes across organisations, sectors and several Member States.

The various acts and initiatives taken so far at EU and national levels only partially address the problems identified and risk creating a legislative patchwork within the internal market, increasing legal uncertainty for both vendors and users of these products and adding unnecessary burden on companies to comply with a number of requirements for similar types of products.

The proposed Regulation would harmonise and streamline the EU regulatory landscape by introducing cybersecurity requirements for products with digital elements and avoid overlapping requirements stemming from different pieces of legislation. This would create greater legal certainty for operators and users across the Union, as well as a better harmonisation of the European single market, creating more viable conditions for operators aiming at entering the EU market.

[1] CJEU Judgment of the Court (Grand Chamber) of 3 December 2019, Czech Republic v European Parliament and Council of the European Union, Case C-482/17, paragraph 35.

[2] CJEU Judgment of the Court (Grand Chamber) of 2 May 2006, United Kingdom of Great Britain and Northern Ireland v European Parliament and Council of the European Union, Case C-217/04, paragraphs 62-63.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Shared competence

Subsidiarity does not apply for policy areas where the Union has ***exclusive*** *competence as defined in Article 3 TFEU*[3]*. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU*[4] *sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU*[5] *sets out the areas for which the Unions has competence only to support the actions of the Member States.*

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[6]**:**

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

The Commission carried out an extensive consultation in preparation of the Impact Assessment report. It benefited from consultation activities already carried out in 2021 for the exploratory study contracted by the Commission and implemented by a consortium made of Wavestone, CEPS and ICF to assess the need for horizontal cybersecurity requirements for digital products. To ensure a high level of coherence and comparability of analysis for all potential policy approaches, a second study led by the same consortium was contracted to collect evidence and conduct analyses in the first half of 2022.

In addition to the Commission open public consultation and feedback on the Call for Evidence, the external contractors collected evidence from a variety of stakeholders through targeted interviews with experts covering different domains, focus groups, two workshops and a targeted online consultation. Moreover, to further support evidence based analysis, the Commission has conducted extensive desk research, covering a wide spectrum of policy studies and reports. They have been quoted in the main body of the Impact Assessment.

Both the explanatory memorandum (section 2) and the impact assessment (chapter 3) contain respectively sections on the principles of subsidiarity, for more details see question 2.2. below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The strong cross-border nature of cybersecurity in general and the growing number of risks and

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN
[5] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

incidents, which have spill-over effects across borders, sectors and products, mean that the objectives of the present intervention cannot effectively be achieved by Member States alone. National approaches in addressing the problems, and in particular approaches introducing mandatory requirements, will create additional legal uncertainty and legal barriers. Companies could be prevented from seamlessly expanding into other Member States, depriving users of the benefits of their products.

Joint action at EU level is therefore necessary to establish a high level of trust among users, increasing the attractiveness of EU products with digital elements. It would also benefit the digital single market and internal market in general by providing legal certainty and achieving a level playing field for manufacturers of products with digital elements.

Ultimately, the Council Conclusions of 23 May 2022 on the development of the European Union's cyber posture[7] call upon the Commission to propose, by the end of 2022, common cybersecurity requirements for connected devices.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

The strong cross-border nature of cybersecurity in general and the growing number of risks and incidents, which have spill-over effects across borders, sectors and products, mean that the objectives of the present intervention cannot effectively be achieved by Member States alone. National approaches in addressing the problems, and in particular approaches introducing mandatory requirements, will only create additional legal uncertainty and legal barriers. Companies could be prevented from seamlessly expanding into other Member States, depriving users of the benefits of their products.

Joint action at EU level is therefore necessary to establish a high level of trust among users, increasing the attractiveness of EU products with digital elements. It would also benefit the digital single market and internal market in general by providing legal certainty and achieving a level playing field for manufacturers of products with digital elements.

Ultimately, the Council Conclusions of 23 May 2022 on the development of the European Union's cyber posture[8] call upon the Commission to propose, by the end of 2022, common cybersecurity requirements for connected devices.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The strong cross-border nature of cybersecurity in general and the growing risks and incidents, which have spill-over effects across borders, sectors and products, mean that the objectives of the present intervention cannot effectively be achieved by Member States alone. Taking into account the global nature of digital product markets, Member States face the same risks with respect to the same digital product on their territory. For example, a recent study on infected IoT products across the internal market has revealed that it is the same nine manufacturers in each country that are responsible for placing the highest number of IoT devices on the market that have been infected as a result of vulnerabilities, concluding that "international collaboration among regulators in various countries is a feasible path. This would not only bundle scarce resources on the side of governments, but is also

[7] Council conclusions on the development of the European Union's cyber posture (2022)
[8] Council conclusions on the development of the European Union's cyber posture (2022)

more likely to influence manufacturer behaviour through collective action. An obvious starting point would be coordination at the level of the European Union."[9]

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[10] or significantly damage the interests of other Member States?

An emerging patchy framework of potentially diverging national rules also risks hampering an open and competitive single market for digital products. Some Member States, such as Germany and Finland have already taken first (non-binding) measures to improve the security of digital products. National approaches in addressing the problems, and in particular approaches introducing mandatory requirements, will only create additional legal uncertainty and legal barriers. Companies could be prevented from seamlessly expanding into other Member States, depriving users of the benefits of their products.

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

Given the lack of negotiation power of individual users on a global products market with large multinational manufacturers (see *section 2.2.5*), regulation at national level would not be effective. In a 2021 report, the Dutch Safety Board concluded that the digital products market "can hardly be influenced by users in the Netherlands alone. Influencing such a global market requires a larger power block, for example at EU or UN level, or based on joint actions by end users."

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

Hardware and software products are increasingly subject to successful cyberattacks, leading to an estimated global annual cost of cybercrime of EUR 5.5 trillion by 2021. Such products suffer from two major problems adding costs for users and the society: (1) a low level of cybersecurity, reflected by widespread vulnerabilities and the insufficient and inconsistent provision of security updates to address them, and (2) an insufficient understanding and access to information by users, preventing them from choosing products with proper cybersecurity features or using them in a secure manner.

The cybersecurity of products with digital elements has a strong cross-border dimension, as products manufactured in one country are often used across the internal market. In addition, incidents initially affecting a single entity or a single Member State often spread within minutes across the entire internal market.

(e) Is the problem widespread across the EU or limited to a few Member States?

The identified problems cumulatively affects the Union as a whole.

[9] Rodríguez et al (2021): "Superspreaders: Quantifying the Role of IoT Manufacturers in Device Infections", *20th Annual Workshop on the Economics of Information Security (WEIS 2021)*, for a more detailed discussion of IoT consumer device security,
p. 8

[10] https://europa.eu/european-union/about-eu/eu-in-brief_en

(f) Are Member States overstretched in achieving the objectives of the planned measure?

Member States have very different levels of capabilities to address the current cybersecurity challenges, some being more mature and better resourced than others. Also, the adoption of different and potentially contradictory rules for product, which are mostly sold across the whole EU, would risk creating a very fragmented regulatory landscape.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

In order to ensure legal certainty and avoid any further fragmentation of product-related requirements on cybersecurity on the internal market, the open public consultation and the targeted consultation have shown a wide overall **support of various stakeholders**, both industry and national authorities for a horizontal intervention setting out cybersecurity requirements for digital products.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

(a) Are there clear benefits from EU level action?

Yes, EU level action could lead to a higher level of cybersecurity for all digital products across the Union, legal certainty for economic operators and more informed decision making for use by the customers of products with digital elements.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

The objectives of the initiative can be better achieved at Union level so as to avoid a further fragmentation of the single market into potentially contradictory national frameworks. A single framework regarding cybersecurity requirements for products with digital elements would provide legal certainty and avoid overlapping or contradictory requirements stemming from different pieces of legislation. Harmonised EU requirements would facilitate compliance for vendors of products with digital elements and create more viable conditions for operators aiming at entering the EU market.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

Users' trust that products with digital elements acquired in any Member State comply with a harmonised set of requirements would increase their trust in and demand for these products. Given the global and cross-border nature of the digital market and the internet, the intervention would reduce negative cross-border spill-overs and costs to society linked to mitigating risks of non-secure products.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The EU initiative would raise the level of cybersecurity for the whole EU by introducing horizontal cybersecurity requirements for products with digital elements. At the same time, the EU initiative will remain for the Member States to carry out the market surveillance and enforcement activities and thus the implementation of the requirements.

(e) Will there be improved legal clarity for those having to implement the legislation?

The proposed Regulation would harmonise the EU regulatory landscape by introducing cybersecurity requirements for products with digital elements and avoid overlapping requirements stemming from different pieces of legislation. This would create greater legal certainty for operators and users across the Union, as well as a better harmonisation of the European single market, creating more viable conditions for operators aiming at entering the EU market.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

As regards the proportionality of the proposed Regulation, the measures in the policy options considered would not go beyond what is needed to achieve the general and specific objectives and would not impose disproportionate costs. More specifically, the intervention considered would ensure that products with digital elements would be secured throughout their whole life cycle and proportionally to the risks faced through objective-oriented and technology neutral requirements that remain reasonable and generally corresponding to the interest of the entities involved.

The essential cybersecurity requirements in the proposal are building on widely used standards, and the standardisation process that will follow would take into account the technical specificities of the products. This means that where needed for a given risk level, security controls would be adapted. Furthermore, the envisaged horizontal rules would only foresee third-party assessment for critical products. This would only include a narrow share of the market for products with digital elements. The impact on SMEs would depend on their presence in the market of these specific product categories.

Regarding the proportionality of the costs for conformity assessment, notified bodies conducting the third party assessments would take the size of the undertaking into account when setting their fees. A reasonable transition period of 24 months to prepare the implementation would also be provided , giving time to the relevant markets to prepare, while providing a clear direction for R&D investments. Any compliance costs for businesses would be outweighed by the benefits brought by a higher level of security of products with digital elements and ultimately an increase of trust of users in these products.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

Yes, as mentioned in the Impact Assessment and the Explanatory Memorandum, the preferred option would ensure the setting out of specific horizontal cybersecurity requirements for all products with digital elements being placed or made available in the internal market, and would be the only option covering the entire digital supply chain. Non-embedded software, often exposed to vulnerabilities, would also be covered by such regulatory intervention, thus ensuring a coherent approach towards all products with digital elements, with a clear share of responsibilities of various economic operators.

This policy option also brings added value by covering duty of care and whole life cycle aspects after the placement of the products with digital elements on the market, to ensure, among others, appropriate information on security support and provision of security updates. This policy option would also come to most effectively complement the recent review of the NIS framework, by ensuring the prerequisites for a strengthened supply chain security. The preferred option would bring significant benefits to the various stakeholders.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The requirements in the EU initiative would not go beyond what is needed to achieve the general and specific objectives and would not impose disproportionate costs. Member States have very different levels of capabilities to address the current cybersecurity challenges, some being more mature and better resourced and technically prepared than others, risking to create a very fragmented regulatory landscape, given the strong cross border nature of the problems the initiative aims to tackle.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

A regulatory intervention would entail the adoption of a regulation and not a directive. This is because, for this particular type of product legislation, a regulation would more effectively address the problems identified and meet the objectives formulated, since it is an intervention that is conditioning the placing on the internal market of a very wide category of products. The transposition process in the case of a directive for such intervention could leave too much room for discretion at national level, potentially leading to lack of uniformity of certain essential cybersecurity requirements, legal uncertainty, further fragmentation or even discriminatory situations cross-border, even more taking account of the fact that the products covered could be of multiple purpose or use and that manufacturers can produce multiple categories of such products.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument og approach?)

The proposal sets out requirements for national authorities responsible for conformity assessment bodies (notified bodies). It leaves the ultimate responsibility for designating and monitoring notified bodies with the Member State. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies.

In accordance with Regulation (EU) 2019/1020, national market surveillance authorities will carry out market surveillance in the territory of that Member State. Member States may choose to designate any existing or new authority to act as market surveillance authority.

Moreover, the proposal establishes maximum levels for administrative fines that should be provided in national laws for non-compliance with the obligations laid down in this Regulation.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

According to the Impact Assessment, the preferred option (which has been chosen for the present EU initiative) would add compliance and enforcement costs for businesses, notified bodies and public authorities, including accreditation and market surveillance authorities. For software developers and hardware manufacturers, it will increase the direct compliance costs for new security requirements, documentation and reporting obligations, leading to aggregated costs amounting to up to EUR 29 billion. End users, including business end users, consumers and citizens may face higher prices of digital products. However, they should be seen against the background of the significant benefits as described above.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

The proposal sets out requirements for national authorities responsible for conformity assessment bodies (notified bodies). It leaves the ultimate responsibility for designating and monitoring notified bodies with the Member State. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies. Member States will also designate the competent market surveillance authority to carry out supervision and enforcement on the territory of each Member State.

Moreover, the proposal establishes maximum levels for administrative fines that should be provided in national laws for non-compliance.