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NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	16753/23
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Subject:	Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020 - Letter sent to the European Parliament

At its meeting on 20 December 2023, the Permanent Representatives Committee

- a) confirmed the agreement on the compromise text of the above-mentioned draft Regulation, as it was reached between the negotiating parties on 30 November 2023 and as it is contained in annex II, together with an accompanying draft joint statement by the European Parliament, the European Commission and the Council of the European Union on ENISA's resources which would be published in the C-Series of the Official Journal, as contained in annex III; and
- b) authorised the Presidency to address the habitual offer letter to the European Parliament.

The letter as it was sent to the European Parliament is set out in the [Annex I](#).

This information is provided in accordance with point 1 h) of note 9493/20 on 'Strengthening legislative transparency'.



S6S 23 / 005638

Brussels, 20/12/2023

Mr Cristian-Silviu BUȘOI
Chair of the Committee on Industry, Research and Energy
European Parliament
Rue Wiertz 60
B-1047 BRUSSELS

Subject: 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

Dear Mr BUȘOI,

Following the informal negotiations on this proposal between the representatives of the three institutions, today the Permanent Representatives Committee agreed with the final compromise text.

I am therefore now in a position to inform you that, should the European Parliament adopt its position at first reading, in accordance with Article 294(3) TFEU, in the exact form of the text set out in the Annex to this letter (subject to revision by the lawyer-linguists of the two institutions), the Council, in accordance with Article 294(4) TFEU, will approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the position of the European Parliament.

On behalf of the Council, I also wish to thank you for your close cooperation which should enable us to reach agreement on this file at first reading.

Yours sincerely

Raúl FUENTES MILANI
Chair of the
Permanent Representatives Committee

Copy:
- Mr Thierry BRETON, Commissioner
- Mr Nicola DANTI, European Parliament rapporteur

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2022/0272 (COD)

**REGULATION (EU) .../...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

of

**on horizontal cybersecurity requirements for products with digital elements,
amending *Regulations (EU) 168/2013 and (EU) 2019/1020*
and *Directive 2020/1828/EC (Cyber Resilience Act)*
(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ *OJ C 100, 16.3.2023, p. 101.*

² OJ C , , p. .

Whereas:

- (1) ***Cybersecurity is one of the key challenges for the Union and the number and variety of connected devices will rise exponentially in the coming years. Cyberattacks represent a matter of public interest as they have a critical impact not just on the Union’s economy, but also on democracy and consumer safety and health.*** It is *therefore* necessary to ***strengthen the Union’s approach to cybersecurity, address cyber resilience at Union level and*** improve the functioning of the internal market by laying down a uniform legal framework for essential cybersecurity requirements for placing products with digital elements on the Union market. Two major problems adding costs for users and society should be addressed: a low level of cybersecurity of products with digital elements, reflected by widespread vulnerabilities and the insufficient and inconsistent provision of security updates to address them, and an insufficient understanding and access to information by users, preventing them from choosing products with adequate cybersecurity properties or using them in a secure manner.
- (2) This Regulation aims to set the boundary conditions for the development of secure products with digital elements by ensuring that hardware and software products are placed on the market with fewer vulnerabilities and that manufactures take security seriously throughout a product’s life cycle. It also aims to create conditions allowing users to take cybersecurity into account when selecting and using products with digital elements, ***for example by improving transparency with regard to the support period of products with digital elements made available on the market.***

- (3) The relevant Union legislation that is currently in force comprises several sets of horizontal rules that address certain aspects linked to cybersecurity from different angles, including measures to improve the security of the digital supply chain. However, the existing Union legislation related to cybersecurity, including *Regulation (EU) 2019/881 of the European Parliament and of the Council*³ and *Directive (EU) 2022/2555 of the European Parliament and of the Council*⁴, does not directly cover mandatory requirements for the security of products with digital elements.
- (4) While the existing Union legislation applies to certain products with digital elements, there is no horizontal Union regulatory framework establishing comprehensive cybersecurity requirements for all products with digital elements. The various acts and initiatives taken thus far at Union and national levels only partially address the identified cybersecurity-related problems and risks, creating a legislative patchwork within the internal market, increasing legal uncertainty for both manufacturers and users of those products and adding an unnecessary burden on *businesses and organisations* to comply with a number of requirements *and obligations* for similar types of products. The cybersecurity of these 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. This makes it necessary to regulate the field at Union level, *to ensure a harmonised regulatory framework and legal certainty for users, organisations and businesses, including micro, small and medium-sized enterprises*. The Union regulatory landscape should be harmonised by introducing cybersecurity requirements for products with digital elements. In addition, certainty for *economic* operators and users should be ensured across the Union, as well as a better harmonisation of the single market *and proportionality for micro, small and medium-sized enterprises*, creating more viable conditions for *economic* operators aiming at entering the Union market.

³ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).

⁴ *Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive) (OJ L 333, 27.12.2022, p. 80).*

- (4a) *The Commission should prepare guidance to assist economic operators, particularly micro, small and medium-sized enterprises, in the application of this Regulation. Guidance should cover inter alia the scope of this Regulation, in particular the notion of remote data processing and the implications for free and open-source software developers, the application of the criteria used to determine the support period of products with digital elements, the interplay between this Regulation and other Union law and the notion of substantial modifications.*
- (5) At Union level, various programmatic and political documents, such as the EU’s Cybersecurity Strategy for the Digital Decade⁵, the Council Conclusions of 2 December 2020 and of 23 May 2022 or the Resolution of the European Parliament of 10 June 2021⁶, have called for specific Union cybersecurity requirements for digital or connected products, with several countries around the world introducing measures to address this issue on their own initiative. In the final report of the Conference on the Future of Europe⁷, citizens called for “a stronger role for the EU in countering cybersecurity threats”. ***In order for the Union to play a leading international role in the field of cybersecurity, it is important to establish an ambitious regulatory framework.***
- (6) To increase the overall level of cybersecurity of all products with digital elements placed on the internal market, it is necessary to introduce objective-oriented and technology-neutral essential cybersecurity requirements for these products that apply horizontally.

⁵ JOIN(2020) 18 final, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=JOIN:2020:18:FIN>.

⁶ 2021/2568(RSP), https://www.europarl.europa.eu/doceo/document/TA-9-2021-0286_EN.html.

⁷ Conference on the Future of Europe – Report on the Final Outcome, May 2022, Proposal 28(2). The Conference was held Between April 2021 and May 2022. It was a unique, citizen-led exercise of deliberative democracy at the pan-European level, involving thousands of European citizens as well as political actors, social partners, civil society representatives and key stakeholders.

- (7) Under certain conditions, all products with digital elements integrated in or connected to a larger electronic information system can serve as an attack vector for malicious actors. As a result, even hardware and software considered as less critical can facilitate the initial compromise of a device or network, enabling malicious actors to gain privileged access to a system or move laterally across systems. Manufacturers should therefore ensure that all connectable products with digital elements are designed and developed in accordance with essential requirements laid down in this Regulation. This includes both products that can be connected physically via hardware interfaces and products that are connected logically, such as via network sockets, pipes, files, application programming interfaces or any other types of software interface. As cybersecurity threats can propagate through various products with digital elements before reaching a certain target, for example by chaining together multiple vulnerability exploits, manufacturers should also ensure the cybersecurity of those products that are only indirectly connected to other devices or networks.
- (8) By setting cybersecurity requirements for placing on the market products with digital elements, the cybersecurity of these products for consumers and for businesses alike will be enhanced. *Those requirements will also ensure that cybersecurity is taken into account throughout supply chains, making final products with digital elements and their components more secure.* This also includes requirements for placing on the market consumer products with digital elements intended for vulnerable consumers, such as toys and baby monitors. *Consumer products with digital elements listed in Annex III present a higher cybersecurity risk by performing a function which carries a significant risk of adverse effects in terms of its intensity and ability to damage the health, security or safety of its users, and will undergo a stricter conformity assessment procedure. This includes smart home products with security functionalities, such as smart door locks, baby monitors and alarm systems, connected toys and personal wearable health technology. Furthermore, the stricter conformity assessment procedure that other products in Annex III and IIIa are required to comply with, will contribute to prevent potential negative impacts on consumers of the exploitation of vulnerabilities.*

- (9) ***The purpose of this Regulation is to ensure a high level of cybersecurity of products with digital elements and their integrated remote data processing solutions. Such remote data processing solutions relating to a product with digital elements are defined as any data processing at a distance for which the software is designed and developed by or on behalf of the manufacturer of the product concerned [REDACTED], and the absence of which would prevent such a product with digital elements from performing one of its functions. This ensures that such products are adequately secured in their entirety by their manufacturers, irrespective of whether data is processed or stored locally on the user’s device or remotely by the manufacturer. At the same time, the processing or storage at a distance is covered only in so far as necessary for a product with digital elements to perform its functions. This could for instance be the case where a mobile application requires access to an application programming interface or a database provided by a service developed by the manufacturer. In such case, the service is therefore in the scope of this Regulation as a remote data processing solution. The requirements concerning the remote data processing solutions under the scope of this Regulation do therefore not entail technical, operational and organisational measures aimed at managing the risks posed to the security of a manufacturer’s network and information systems as a whole.***
- (9a) ***Cloud solutions constitute remote data processing solutions within the meaning of this Regulation only if they meet the definition thereof. For example, cloud enabled functionalities provided by the manufacturer of smart home devices that enable users to control the device at a distance should fall within the scope of this Regulation. On the other hand, websites that do not support the functionality of a product with digital elements, or cloud services designed and developed outside the responsibility of a manufacturer of a product with digital elements are not in the scope of this Regulation. Directive (EU) 2022/2555 applies to cloud computing services and cloud service models, such as Software-as-a-Service (SaaS), Platform-as-a-Service (PaaS) or Infrastructure-as-a-Service (IaaS). All entities providing cloud computing services in the Union which qualify as medium-sized enterprises under Article 2 of the Annex to Commission Recommendation 2003/361/EC¹, or exceed the ceilings for medium-sized enterprises provided for in paragraph 1 of that Article, fall in the scope of that Directive.***

(9b) *In line with the objective of this Regulation to remove obstacles to the free movement of products with digital elements, Member States should not impede, for the matters covered by this Regulation, the making available on the market of products with digital elements which comply with this Regulation. Therefore, for matters harmonised by this Regulation, Member States cannot impose additional cybersecurity requirements for the making available on the market of products with digital elements. Any entity, public or private, can however establish additional requirements to those laid down by this Regulation for the procurement or use of those products for its specific purposes and can therefore choose to use products with digital elements that meet stricter or more specific cybersecurity requirements than those applicable for the making available on the market under this Regulation. Without prejudice to Directive (EU) 2014/24 and Directive (EU) 2014/25, when procuring products with digital elements, which must comply with the cybersecurity requirements, including those relating to vulnerability handling, as laid down by this Regulation, Member States should ensure that such requirements are included in public procurement and that the manufacturers' ability to effectively apply cybersecurity measures and manage cyber threats are also taken into consideration. Furthermore, Directive (EU) 2022/2555 sets out cybersecurity risk-management measures for essential and important entities that could entail supply chain security measures that require the use of products with digital elements meeting stricter cybersecurity requirements than those laid down by this Regulation. In line with Directive (EU) 2022/2555 and its minimum harmonisation principle, Member States may therefore impose additional cybersecurity requirements for the use of ICT products by essential or important entities under the scope of that Directive in order to ensure a higher level of cybersecurity, provided that such requirements are consistent with Member States' obligations laid down in Union law. Matters not covered by this Regulation can include non-technical factors relating to products with digital elements and the manufacturers thereof. Member States may therefore lay down national measures, including restrictions on products with digital elements or suppliers of such products, that take account of non-technical factors. National measures relating to such factors must comply with Union law.*

- (9c) *This Regulation should be without prejudice to the Member States' responsibility for safeguarding national security, in compliance with Union law. Member States should be able to subject products with digital elements that will be used for defence or national security purposes, to additional measures provided that such measures are consistent with Member States' obligations laid down in Union law.*
- (10) *This Regulation applies to economic operators only in relation to products with digital elements made available on the market, hence supplied for distribution or use on the Union market in the course of a commercial activity. The supply in the course of a commercial activity might be characterized not only by charging a price for a product, but also by charging a price for technical support services **when this does not serve only the recuperation of actual costs, or by an intention to monetise, for instance** by providing a software platform through which the manufacturer monetises other services, **by requiring as a condition for use the processing** of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software, **or by accepting donations exceeding the costs associated with the design, development and provision of a product with digital elements. Accepting donations without the intention of making a profit should not be considered to be a commercial activity.***
- (10a) *Products provided as part of the delivery of a service for which a fee is charged solely to recover the actual costs directly related to the operation of that service, such as may be the case with certain products provided by public administration entities, should not be considered on those grounds alone a commercial activity for the purposes of this Regulation. Furthermore, products with digital elements which are developed or modified by a public administration entity exclusively for its own use should not be considered as made available on the market as defined by this Regulation.*

(10b) Software and data that are openly shared and where users can freely access, use, modify and redistribute them or modified versions thereof, can contribute to research and innovation in the market. To foster the development and deployment of free and open-source software, in particular by microenterprises and small, medium-sized enterprises, including start-ups, and not-for-profit organisations, academic research and individuals, the application of this Regulation to free and open-source software products supplied for distribution or use in the course of a commercial activity should take into account the nature of the different development models of software distributed and developed under free and open-source software licences.

(10c) *Free and open-source software is understood as software the source code of which is openly shared and the license of which provides for all rights to make it freely accessible, usable, modifiable and redistributable. Free and open-source software is developed, maintained, and distributed openly, including via online platforms. In relation to the economic operators covered by this regulation, only free and open-source software made available on the market, and therefore supplied for distribution or use in the course of a commercial activity should be covered by this Regulation. The mere circumstances under which the product has been developed, or how the development has been financed should therefore not be taken into account when determining the commercial or non-commercial nature of that activity. More specifically, for the purpose of this Regulation and in relation to the economic operators referred therein, to ensure that there is a clear distinction between the development and the supply phases, the provision of free and open-source software products with digital elements that are not monetised by their manufacturers is not considered a commercial activity. Furthermore, the supply of products with digital elements qualifying as free and open-source software components intended for integration by other manufacturers into their own products with digital elements should only be considered as making available on the market if the component is monetised by its original manufacturer. For instance, the mere fact that an open-source software product with digital elements receives financial support by manufacturers or that manufacturers contribute to the development of such a product should not in itself determine that the activity is of commercial nature. In addition, the mere presence of regular releases in itself does not lead to the conclusion that a product is supplied in the course of a commercial activity. Finally, for the purpose of this Regulation, the development of products with digital elements qualifying as free and open-source software by not-for-profit organisations should not be considered a commercial activity as long as the organisation is set up in a way that ensures that all earnings after cost are used to achieve not-for-profit objectives. This Regulation does not apply to natural or legal persons who contribute source code to free and open-source products that are not under their responsibility.*

(10d) Taking into account the cybersecurity importance of many free and open-source software products with digital elements that are published but, within the meaning of this Regulation, not made available on the market, legal persons which provide support on a sustained basis for the development of such products with digital elements qualifying as free and open-source software, which are intended for commercial activities, and play a main role in ensuring the viability of those products ('open-source software stewards') should be subject to a light-touch and tailor-made regulatory regime. This includes certain foundations as well as entities that develop and publish free and open-source software in a business context, such as not-for-profit entities developing free and open-source software in a business context. This regulatory regime should take account of their specific nature and compatibility with the type of obligations imposed. It should only cover free and open-source software products with digital elements that are ultimately intended for commercial activities, such as for integration into commercial services or into monetised products with digital elements. For the purpose of the light-touch and tailor-made regulatory regime, an intention for integration into monetised products includes cases where manufacturers that integrate a component into their own products with digital elements either contribute to the development of that component in a regular manner or provide regular financial assistance to ensure the continuity of the software product. The provision of sustained support to the development of a product with digital elements includes but is not limited to the hosting and managing of software development collaboration platforms, the hosting of source code or software, the governing or managing of free and open-source software products with digital elements as well as the steering of the development of such products. Given that the light-touch and tailor-made regulatory regime does not subject open-source software stewards to the same obligations as manufacturers under this Regulation, they should not be able to affix the CE marking to the products with digital elements whose development they support.

- (10e)** *The sole act of hosting products with digital elements on open repositories, including through package managers or on collaboration platforms, does not in itself constitute making available on the market of a product with digital elements. Providers of such services should only be considered distributors if they make such software available on the market and hence supply it for distribution or use on the Union market in the course of a commercial activity.*
- (10f)** *In order to support and facilitate the due diligence of manufacturers that integrate free and open-source software components that are not subject to the essential requirements laid down in this Regulation into their products with digital elements, the Commission should be able to establish voluntary security attestation programmes, either by a delegated act supplementing this Regulation or by requesting a European cybersecurity certification scheme pursuant to Article 48 of Regulation (EU) 2019/881 that takes into account the specifics of the free and open-source software development models. The security attestation programmes should be conceived in such a way that not only legal or natural persons developing or contributing to the development of a product with digital elements qualifying as free and open-source software can initiate or finance an attestation but also third-parties, such as manufacturers that integrate such products into their own products, users, or European and national public administrations.*
- (10g)** *In view of the public cybersecurity objectives of this Regulation and in order to improve the situational awareness of Member States as regards the Union's dependency on software components and in particular on potentially free and open-source software components, the administrative cooperation group (ADCO) established by this Regulation should be able to decide to jointly undertake a Union dependency assessment. Market surveillance authorities should be able to request manufacturers of categories of products with digital elements established by the ADCO to submit the software bills of materials (SBOMs) that they have generated pursuant to this Regulation. In order to protect the confidentiality of SBOMs, market surveillance authorities should submit relevant information about dependencies to the ADCO in an anonymised and aggregated manner.*

(10h) *The effectiveness of the implementation of this Regulation will also depend on the availability of adequate cybersecurity skills. At Union level, various programmatic and political documents, including the Commission Communication on Closing the cybersecurity talent gap to boost the EU's competitiveness, growth and resilience⁸ ('The Cybersecurity Skills Academy') and the Council Conclusions on the EU Policy on Cyber Defence⁹, acknowledged the cybersecurity skills gap in the Union and the need to address such challenges as a matter of priority, in both the public and private sectors. In view of ensuring an effective implementation of this Regulation, Member States should ensure that adequate resources are available for the appropriate staffing of the market surveillance authorities and conformity assessment bodies to perform their tasks as laid down by this Regulation. These measures should enhance workforce mobility in the cyber security field and their associated career pathways. They should also contribute to making the cyber security workforce more resilient and inclusive, also in terms of gender. Member States should therefore take measures to ensure that these tasks are carried out by adequately trained professionals, with the necessary cybersecurity skills. Similarly, manufacturers should ensure that their staff has the necessary skills to comply with their respective obligations laid down by this Regulation. Member States and the Commission, in line with their respective prerogatives and competences and the specific tasks set out by this Regulation, should take measures to support manufacturers and in particular micro, small and medium sized enterprises and start-ups, including areas such as skill development and, in view of the compliance with the obligations imposed by this Regulation. Furthermore, as Directive (EU) 2022/2555 requires Member States to adopt policies promoting and developing training and cybersecurity skills as part of the national cybersecurity strategies, Member States may consider, when adopting such strategies, to also address the cybersecurity skills needs, including those relating to re-skilling and up-skilling, resulting from this Regulation.*

⁸ *COM(2023) 207 final.*

⁹ *Council Conclusions on the EU Policy on Cyber Defence of 22 May 2023, 9618/23.*

- (11) A secure Internet is indispensable for the functioning of critical infrastructures and for society as a whole. ■ Directive *(EU) 2022/2555* aims at ensuring a high level of cybersecurity of services provided by essential and important entities, including digital infrastructure providers that support core functions of the open Internet, ensure Internet access and Internet services. It is therefore important that the products with digital elements necessary for digital infrastructure providers to ensure the functioning of the Internet are developed in a secure manner and that they comply with well-established Internet security standards. This Regulation, which applies to all connectable hardware and software products, also aims at facilitating the compliance of digital infrastructure providers with the supply chain requirements under ■ Directive *(EU) 2022/2555* by ensuring that the products with digital elements that they use for the provision of their services are developed in a secure manner and that they have access to timely security updates for such products.

(12) Regulation (EU) 2017/745 of the European Parliament and of the Council¹⁰ lays down rules on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council¹¹ lays down rules on *in vitro* diagnostic medical devices. Both Regulations address cybersecurity risks and follow particular approaches that are also addressed in this Regulation. More specifically, Regulations (EU) 2017/745 and (EU) 2017/746 lay down essential requirements for medical devices that function through an electronic system or that are software themselves. Certain non-embedded software and the whole life cycle approach are also covered by those Regulations. These requirements mandate manufacturers to develop and build their products by applying risk management principles and by setting out requirements concerning IT security measures, as well as corresponding conformity assessment procedures. Furthermore, specific guidance on cybersecurity for medical devices is in place since December 2019, providing manufacturers of medical devices, including *in vitro* diagnostic devices, with guidance on how to fulfil all the relevant essential requirements of Annex I to those Regulations with regard to cybersecurity.¹² Products with digital elements to which either of those Regulations apply should therefore not be subject to this Regulation.

(12a) Products with digital elements that are developed or modified exclusively for national security or defence purposes or products that are specifically designed to process classified information fall outside the scope of this Regulation. Member States are encouraged to ensure the same or a higher level of protection for those products as for those falling within the scope of this Regulation.

¹⁰ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

¹¹ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

¹² MDCG 2019-16, endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745.

- (13) Regulation (EU) 2019/2144 of the European Parliament and of the Council¹³ establishes requirements for the type-approval of vehicles, and of their systems and components, introducing certain cybersecurity requirements, including on the operation of a certified cybersecurity management system, on software updates, covering organisations policies and processes for cyber risks related to the entire *life cycle* of vehicles, equipment and services in compliance with the applicable United Nations regulations on technical specifications and cybersecurity¹⁴, and providing for specific conformity assessment procedures. In the area of aviation, the principal objective of Regulation (EU) 2018/1139 of the European Parliament and of the Council¹⁵ is to establish and maintain a high uniform level of civil aviation safety in the Union. It creates a framework for essential requirements for airworthiness for aeronautical products, parts, equipment, including software that take into account obligations to protect against information security threats. Products with digital elements to which Regulation (EU) 2019/2144 applies and those products certified in accordance with Regulation (EU) 2018/1139 are therefore not subject to the essential requirements and conformity assessment procedures set out in this Regulation. The certification process under Regulation (EU) 2018/1139 ensures the level of assurance aimed for by this Regulation.

¹³ Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).

¹⁴ UN Regulation No 155 – Uniform provisions concerning the approval of vehicles with regard to cybersecurity and cybersecurity management system [2021/387].

¹⁵ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

(14) This Regulation lays down horizontal cybersecurity rules which are not specific to sectors or certain products with digital elements. Nevertheless, sectoral or product-specific Union rules could be introduced, laying down requirements that address all or some of the risks covered by the essential requirements laid down by this Regulation. In such cases, the application of this Regulation to products with digital elements covered by other Union rules laying down requirements that address all or some of the risks covered by the essential requirements set out in Annex I of this Regulation may be limited or excluded where such limitation or exclusion is consistent with the overall regulatory framework applying to those products and where the sectoral rules achieve **at least** the same level of protection as the one provided for by this Regulation. The Commission is empowered to adopt delegated acts to **supplement** this Regulation by identifying such products and rules. For existing Union legislation where such limitations or exclusions should apply, this Regulation contains specific provisions to clarify its relation with that Union legislation.

(14a) In order to ensure that products made available on the market can be repaired effectively and their durability extended, an exemption should be provided for spare parts. This should be the case both for spare parts that have the purpose of repairing legacy products made available before the date of application of this Regulation as well as for spare parts that have already undergone a conformity assessment procedure pursuant to this Regulation.

- (15) **Commission** Delegated Regulation (EU) 2022/30¹⁶ specifies that the essential requirements set out in Article 3(3), point (d) (network harm and misuse of network resources), point (e) (personal data and privacy) and point (f) (fraud) of Directive 2014/53/EU apply to certain radio equipment. [Commission implementing decision XXX/2022 on a standardisation request to the European Standardisation Organisations] lays down requirements for the development of specific standards further specifying how these three essential requirements should be addressed. The essential requirements laid down by this Regulation include all the elements of the essential requirements referred to in Article 3(3), points (d), (e) and (f) of Directive 2014/53/EU. Further, the essential requirements laid down in this Regulation are aligned with the objectives of the requirements for specific standards included in that standardisation request. Therefore, **when** the Commission repeals or amends Delegated Regulation (EU) 2022/30 with the consequence that it ceases to apply to certain products subject to this Regulation, the Commission and the European Standardisation Organisations should take into account the standardisation work carried out in the context of Commission Implementing Decision C(2022)5637 on a standardisation request for the RED Delegated Regulation 2022/30 in the preparation and development of harmonised standards to facilitate the implementation of this Regulation. **During the transition period of this Regulation, the Commission should provide guidance to manufacturers subject to this Regulation who are also subject to the Delegated Regulation (EU) 2022/30 to facilitate the demonstration of compliance with the two regulations.**

¹⁶ **Commission Delegated Regulation (EU) 2022/30 of 29 October 2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive (OJ L 7, 12.1.2022, p. 6).**

- (16) **Council** Directive 85/374/EEC¹⁷ is complementary to this Regulation. That Directive sets out liability rules for defective products so that injured persons can claim compensation when a damage has been caused by defective products. It establishes the principle that the manufacturer of a product is liable for damages caused by a lack of safety in their product irrespective of fault ('strict liability'). Where such a lack of safety consists in a lack of security updates after placing the product on the market, and this causes damage, the liability of the manufacturer could be triggered. Obligations for manufacturers that concern the provision of such security updates should be laid down in this Regulation.
- (17) This Regulation should be without prejudice to Regulation (EU) 2016/679 of the European Parliament and of the Council¹⁸, including to provisions for the establishment of data protection certification mechanisms and of data protection seals and marks, for the purpose of demonstrating compliance of processing operations by controllers and processors with that Regulation. Such operations could be embedded in a product with digital elements. Data protection by design and by default, and cybersecurity in general, are key elements of Regulation (EU) 2016/679. By protecting consumers and organisations from cybersecurity risks, the essential cybersecurity requirements laid down in this Regulation, are also to contribute to enhancing the protection of personal data and privacy of individuals. Synergies on both standardisation and certification on cybersecurity aspects should be considered through the cooperation between the Commission, the European Standardisation Organisations, the European Union Agency for Cybersecurity (ENISA), the European Data Protection Board (EDPB) established by Regulation (EU) 2016/679, and the national data protection supervisory authorities. Synergies between this Regulation and the Union data protection law should also be created in the area of market surveillance and enforcement. To this end, national market surveillance authorities appointed under this Regulation should cooperate with authorities supervising Union data protection law. The latter should also have access to information relevant for accomplishing their tasks.

¹⁷ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

¹⁸ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)(OJ L 119, 4.5.2016, p. 1).

- (18) To the extent that their products fall within the scope of this Regulation, issuers of European Digital Identity Wallets as referred to in Article [Article 6a(2) of Regulation (EU) No 910/2014, as amended by Proposal for a Regulation amending Regulation (EU) No 910/2014 as regards establishing a framework for a European Digital Identity], should comply with both the horizontal essential requirements established by this Regulation and the specific security requirements established by Article [Article 6a of Regulation (EU) No 910/2014, as amended by Proposal for a Regulation amending Regulation (EU) No 910/2014 as regards establishing a framework for a European Digital Identity]. In order to facilitate compliance, wallet issuers should be able to demonstrate the compliance of European Digital Identity Wallets with the requirements set out respectively in both acts by certifying their products under a European cybersecurity certification scheme established under Regulation (EU) 2019/881 and for which the Commission specified via delegated act a presumption of conformity for this Regulation, in so far as the certificate, or parts thereof, covers those requirements.

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- (18a)** *When integrating components sourced from third parties in products with digital elements during the design and development phase, in order to ensure that the products are designed, developed and produced in accordance with the essential requirements provided for in Annex I to this Regulation, manufacturers should exercise due diligence with regard to those components, including free and open-source software components that have not been made available on the market. The appropriate level of due diligence depends on the nature and the level of cybersecurity risk associated with a given component, and, for this purpose, should take into account one or more of the following actions: verifying, as applicable, that the manufacturer of a component has demonstrated conformity with this Regulation, including by checking if the component already carries the CE mark; verifying that a component receives regular security updates, such as by checking security updates history, verifying that a component is free from vulnerabilities registered in the European vulnerability database or other publicly accessible vulnerability databases, or carrying out additional security tests. The vulnerability handling obligations in this Regulation, which the manufacturers have to comply with when placing a product with digital elements on the market and for the support period, apply to products with digital elements in their entirety, including to all integrated components. Where, in the exercise of due diligence, the manufacturer of the product identifies a vulnerability in a component, including in a free and open-source component, it should inform the person or entity manufacturing or maintaining the component, address and remediate the vulnerability, and, where applicable, provide the person or entity with the applied security fix.*
- (18b)** *Immediately after the transition period for the application of this Regulation, a manufacturer of a product with digital elements that integrates one or several components sourced from third parties which are also subject to this Regulation may not be able to verify, as part of its due diligence obligation, that the manufacturers of those components have demonstrated conformity with this Regulation by checking, for instance, if the components already carry the CE mark. This may be because the components could have been integrated before this Regulation becomes applicable to the manufacturers of those components. In such a case, the manufacturer integrating such components should exercise due diligence through other means.*

- (20) Products with digital elements should bear the CE marking to *visibly, legibly and indelibly* indicate their conformity with this Regulation so that they can move freely within the internal market. Member States should not create unjustified obstacles to the placing on the market of products with digital elements that comply with the requirements laid down in this Regulation and bear the CE marking. ***Furthermore, at trade fairs, exhibitions and demonstrations or similar events, Member States should not prevent the presentation and use of a product with digital elements which does not comply with this Regulation, including its prototypes.***
- (21) In order to ensure that manufacturers can release software for testing purposes before subjecting their products to conformity assessment, Member States should not prevent the making available of unfinished software, such as alpha versions, beta versions or release candidates, as long as the version is only made available for the time necessary to test it and gather feedback. Manufacturers should ensure that software made available under these conditions is only released following a risk assessment and that it complies to the extent possible with the security requirements relating to the properties of products with digital elements imposed by this Regulation. Manufacturers should also implement the vulnerability handling requirements to the extent possible. Manufacturers should not force users to upgrade to versions only released for testing purposes.

- (22) In order to ensure that products with digital elements, when placed on the market, do not pose cybersecurity risks to persons and organisations, essential requirements should be set out for such products. *These essential requirements, including vulnerability management handling requirements, apply to each individual product with digital elements when placed on the market, irrespective of whether the product with digital elements is manufactured as an individual unit or in series. For example, for a product type, each individual product with digital elements should have received all security patches or updates available to address relevant security issues at the time when it is placed on the market.* When the products are subsequently modified, by physical or digital means, in a way that is not foreseen by the manufacturer *in the initial risk assessment* and that may imply that they no longer meet the relevant essential requirements, the modification should be considered as substantial. For example, ■ repairs could be assimilated to maintenance operations provided that they do not modify a product already placed on the market in such a way that compliance with the applicable requirements may be affected, or that the intended *purpose* for which the product has been assessed may be changed. ■

(22a) As is the case for physical repairs or modifications, a product with digital elements should be considered as substantially modified by a software change where the software update modifies the intended purpose of that product and these changes were not foreseen by the manufacturer in the initial risk assessment, or where the nature of the hazard has changed or the level of risk has increased because of the software update, and this updated version of the product is made available on the market. Where security updates, which are designed to decrease the level of risk of a product with digital elements, do not modify the intended purpose of a product, they are not considered a substantial modification. This usually includes situations where security updates entail only minor adjustments of the source code. For example, this could be the case where a security update addresses a known vulnerability, including by modifying functions or the performance of a product with digital elements for the sole purpose of decreasing the level of cybersecurity risk. Similarly, minor functionality updates, such as visual enhancements, the addition of new languages to the user interface or of a new set of pictograms, should generally not be considered to be substantial modifications. Conversely, where feature updates modify the original intended functions or the type or performance of a product and meet above criteria, they should be considered a substantial modification, as the addition of new features typically leads to a broader attack surface, thereby increasing the risk. For example, this could be the case where a new input element is added to an application, requiring the manufacturer to ensure adequate input validation. In assessing whether a feature update is considered a substantial modification it is not relevant whether it is provided as a separate update or in combination with a security update. The Commission should issue guidelines on how to determine what constitutes a substantial modification.

- (22b) *Taking into account the iterative nature of software development, manufacturers that have placed subsequent versions of a software product on the market as a result of subsequent substantial modifications of that product should be able to provide security updates for the entire duration of the support period only for the version of the software product that they have last placed on the market. They should be able to do so only if the users of the relevant previous product versions have access to the product version last placed on the market free of charge and do not incur additional costs to adjust the hardware and software environment in which they operate the product. This could for instance be the case where a desktop operating system upgrade does not imply new hardware requirements, such as a faster central processing unit or more memory. Nonetheless, the manufacturer should continue to comply, for the entire duration of the support period, with other vulnerability handling requirements, such as having a policy on coordinated vulnerability disclosure or measures to facilitate the sharing of information about potential vulnerabilities for all subsequent substantially modified versions of the software product placed on the market. Manufacturers should be able to provide minor security or functionality updates that do not constitute a substantial modification only for the latest version or subversion of a software product that has not been substantially modified. At the same time, where a hardware product, such as a smartphone, is not compatible with the latest version of the operating system it was originally shipped with, the manufacturer should continue to provide security updates at least for the latest compatible version of the operating system for the entire duration of the support period.*
- (23) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, whenever a substantial modification occurs that may affect the compliance of a product with this Regulation or when the intended purpose of that product changes, it is appropriate that the compliance of the product with digital elements is verified and that, where applicable, it undergoes a new conformity assessment. Where applicable, if the manufacturer undertakes a conformity assessment involving a third party, changes that might lead to substantial modifications should be notified to the third party.

- (24) Refurbishing, maintaining and repairing of a product with digital elements, as defined in the Regulation [Eco-design Regulation], does not necessarily lead to a substantial modification of the product, for instance if the intended **purpose** and functionalities are not changed and the level of risk remains unaffected. However, upgrading a product by the manufacturer might lead to changes in the design and development of the product and therefore might affect the intended **purpose** and the compliance of the product with the requirements set out in this Regulation.
- (25) Products with digital elements should be considered **important** if the negative impact of the exploitation of potential cybersecurity vulnerabilities in the product can be severe due to, amongst others, the cybersecurity-related functionality **or a function having a significant risk of adverse effects in terms of its intensity and ability to disrupt, control or cause damage to a large number of other products with digital elements or to the health, security or safety of its users through direct manipulation, such as a central system function or processing of personal data**. In particular, vulnerabilities in products with digital elements that have a cybersecurity-related functionality, such as **boot managers**, can lead to a propagation of security issues throughout the supply chain. The severity of the impact of a cybersecurity incident may also increase when **the product primarily performs a central system function, including network management, configuration control, virtualisation or processing of personal data**.

- (26) *Certain categories of* products with digital elements should be subject to stricter conformity assessment procedures, while keeping a proportionate approach. For this purpose, *important* products with digital elements should be divided into two classes, reflecting the level of cybersecurity risk linked to these categories of products. *The important products with digital elements listed in class I of Annex III to this Regulation either have a cybersecurity-related functionality or a function which carries a significant risk of adverse effects in terms of its intensity and ability to disrupt, control or cause damage to a large number of other products with digital elements or to the health, security or safety of its users through direct manipulation, such as a central system function or processing of personal data.* A potential cyber incident involving *important* products in class II might lead to greater negative impacts than an incident involving *important* products in class I, for instance due to the nature of their cybersecurity-related function or *the performance of another function which carries a significant risk of adverse effects*, and therefore should undergo a stricter conformity assessment procedure. *As an indication of such greater negative impacts, product categories listed in class II could either perform a cybersecurity-related functionality or another function which carries a significant risk of adverse effects that are higher than for those products included in class I or meet both of the aforementioned criteria.*
- (27) The categories of *important* products with digital elements referred to in Annex III of this Regulation should be understood as the products which have the core functionality of the type that is listed in Annex III to this Regulation. For example, Annex III to this Regulation lists products which are defined by their core functionality as *firewalls, intrusion detection or prevention systems* in class II. As a result, *firewalls, intrusion detection or prevention systems* are subject to mandatory third-party conformity assessment. This is not the case for other products not explicitly referred to in Annex III to this Regulation which may integrate *firewalls, intrusion detection or prevention systems*. The Commission should adopt *an implementing act* to specify the *technical description* of the product categories covered under class I and class II as set out in Annex III.

(27a) *The categories of critical products with digital elements listed in Annex IIIa to this Regulation have a cybersecurity-related functionality and perform a function which carries a significant risk of adverse effects in terms of its intensity and ability to disrupt, control or damage a large number of other products with digital elements through direct manipulation. Furthermore, those product categories are considered to be critical dependencies for essential entities of a type referred to in Article 3 of Directive (EU) 2022/2555. The categories of products with digital elements listed in Annex IIIa to this Regulation, due to their criticality, already widely use various forms of certification, and are also covered by the European Common Criteria-based cybersecurity certification scheme set out in the [Commission Implementing Regulation (EU) No .../... of XXX on the European Common Criteria-based cybersecurity certification scheme] (EUCC). Therefore, in order to ensure a common adequate cybersecurity protection of these products with digital elements in the Union, it could be adequate and proportionate to subject these products, by means of a delegated act, to mandatory European cybersecurity certification where a relevant certification scheme covering those products is already in place and an impact assessment has been carried out by the Commission. The assessment of the potential market impact of the envisaged mandatory certification should consider both the supply and demand side, including whether there is sufficient demand for the products with digital elements concerned from both Member States and users, for European cybersecurity certification to be required, as well as the purposes for which the products are intended to be used, such as critical dependencies by essential entities of a type referred to in Article 3 of Directive (EU) 2022/2555. The assessment should also analyse the potential effects of the mandatory certification on the availability of those products on the internal market, as well as the supply and demand side and the capabilities and the readiness of the Member States for the implementation of the relevant European cybersecurity certification schemes.*

- (27b) Delegated acts requiring mandatory European cybersecurity certification should specify the products with digital elements that have the core functionality of a product category listed in Annex IIIa that are to be subject to mandatory certification, as well as the assurance level at least substantial. The required assurance level should be proportionate to the level of cybersecurity risk associated with the product with digital elements. For instance, where the product has the core functionality of a product category listed in Annex IIIa and is intended for the use in a sensitive or critical environment, such as products intended for the use of essential entities of a type referred to in Article 3 to Directive (EU) 2022/2555, it may require the highest assurance level.*
- (27c) In order to ensure a common adequate cybersecurity protection in the Union of products with digital elements that have the core functionality of a product category listed in Annex IIIa, the Commission should also be empowered to adopt delegated acts to amend Annex IIIa by adding further or removing categories of products with digital elements for which the manufacturers could be required to obtain a European cybersecurity certificate under a European cybersecurity certification scheme pursuant to Regulation (EU) 2019/881 to demonstrate conformity with this Regulation. A new category of products with digital elements can be added to those categories if there is a critical dependency on it of essential entities of a type referred to in Article 3 of Directive (EU) 2022/2555 or, if affected by cybersecurity incidents or when containing exploited vulnerabilities, this can lead to disruptions for critical supply chains. When assessing the need for adding or removing categories of products with digital elements by means of a delegated act, the Commission may take into account whether the Member States identified at national level products with digital elements that have a critical role for the resilience of essential entities of a type referred to in Article 3 of Directive (EU) 2022/2555 and which increasingly face supply chain cyber attacks, with potential serious disruptive effects. Furthermore, the Commission may take into account the outcome of the Union level coordinated security risk assessment of critical supply chains as per Article 22 of Directive (EU) 2022/2555.*

- (27d) *The Commission should ensure that a wide range of relevant stakeholders are consulted in a structured and regular manner when preparing measures for the implementation of this regulation. This is particularly the case where the Commission assesses the need for potential updates to the list of categories of important or critical products with digital elements where relevant manufacturers should be consulted and their views taken into account in order to analyse the cybersecurity risks as well as the balance of costs and benefits of designating such categories of products as important or critical.*
- (28) This Regulation addresses cybersecurity risks in a targeted manner. Products with digital elements might, however, pose other safety risks, that are not *always* related to cybersecurity *but can be a consequence of a security breach*. Those risks should continue to be regulated by other relevant Union *harmonisation* legislation. If no other Union harmonisation legislation is applicable, they should be subject to Regulation (EU) 2023/988. Therefore, in light of the targeted nature of this Regulation, as a derogation from Article 2(1), third subparagraph, point (b), of Regulation (EU) 2023/988, Chapter III, Section 1, Chapters V and VII, and Chapters IX to XI of Regulation (EU) 2023/988 should apply to products with digital elements with respect to safety risks not covered by this Regulation, if those products are not subject to specific requirements imposed by other Union harmonisation legislation within the meaning of Article 3, point (27) of Regulation (EU) 2023/988.

(29) Products with digital elements classified as high-risk AI systems according to Article 6 of Regulation [the AI Regulation] which fall within the scope of this Regulation should comply with the essential requirements set out in this Regulation. When those high-risk AI systems fulfil the essential requirements of this Regulation, they should be deemed compliant with the cybersecurity requirements set out in Article [Article 15] of Regulation [the AI Regulation] in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued under this Regulation. ***For this purpose, the assessment of the cybersecurity risks associated to a product with digital elements classified as high-risk AI system according to [the AI Regulation] that are to be taken into account during the planning, design, development, production, delivery and maintenance phases of such product, as requested by this Regulation, should consider risks to the cyber resilience of an AI system as regards attempts by unauthorised third parties to alter its use, behaviour or performance, including AI specific vulnerabilities such as data poisoning or adversarial attacks, as well as, as relevant, risks to fundamental rights, in accordance with [AI Regulation].*** As regards the conformity assessment procedures relating to the essential cybersecurity requirements of a product with digital elements covered by this Regulation and classified as a high-risk AI system, the relevant provisions of Article 43 of Regulation [the AI Regulation] should apply as a rule instead of the respective provisions of this Regulation. However, this rule should not result in reducing the necessary level of assurance for ***important and*** critical products with digital elements ***as referred to in Annexes III and IIIa*** to this Regulation. Therefore, by way of derogation from this rule, high-risk AI systems that fall within the scope of the Regulation [the AI Regulation] and are also ***important and*** critical products with digital elements ***as referred to in Annex III and IIIa*** to this Regulation and to which the conformity assessment procedure based on internal control referred to in Annex VI of the Regulation [the AI Regulation] applies, should be subject to the conformity assessment provisions of this Regulation in so far as the essential requirements of this Regulation are concerned. In this case, for all the other aspects covered by Regulation [the AI Regulation] the respective provisions on conformity assessment based on internal control set out in Annex VI to Regulation [the AI Regulation] should apply.

(30) ***Manufacturers of products falling within the scope of Regulation (EU) 2023/1230 of the European Parliament and of the Council¹⁹ which are also products with digital elements within the meaning of this Regulation should comply with both the essential requirements established by this Regulation and the essential health and safety requirements set out in Regulation (EU) 2023/1230. The essential requirements under this Regulation and certain essential requirements of Regulation (EU) 2023/1230 might address similar cybersecurity risks. Therefore, the compliance with the essential requirements under this Regulation could facilitate the compliance with the essential requirements that also cover certain cybersecurity risks as set out in Regulation (EU) 2023/1230, and in particular those regarding the protection against corruption and safety and reliability of control systems set out in sections 1.1.9 and 1.2.1 of Annex III in that Regulation. Such synergies have to be demonstrated by the manufacturer, for instance by applying where available harmonised standards or other technical specifications covering relevant cybersecurity essential requirements following a risk assessment covering those cybersecurity risks. The manufacturer should also follow the applicable conformity assessment procedures set out in this Regulation and Regulation (EU) 2023/1230. The Commission and the European Standardisation Organisations, in the preparatory work supporting the implementation of this Regulation and of Regulation (EU) 2023/1230 and the related standardisation processes, should promote consistency in how the cybersecurity risks are expected to be assessed and in how those risks are to be covered by harmonised standards for the respective essential requirements. In particular, the Commission and the European Standardisation Organisations should take into account this Regulation in the preparation and development of harmonised standards to facilitate the implementation of Regulation (EU) 2023/1230 as regards in particular the cybersecurity aspects related to the protection against corruption and safety and reliability of control systems set out in Sections 1.1.9 and 1.2.1 of Annex III to that Regulation. The Commission should provide guidance to support the manufacturers subject to this Regulation who are also subject to Regulation (EU) 2023/1230 and in particular to facilitate the demonstration of compliance with relevant essential requirements of these two regulations.***

¹⁹ ***Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1).***

- (31) Regulation [European Health Data Space Regulation proposal] complements the essential requirements laid down in this Regulation. The electronic health record systems (‘EHR systems’) falling under the scope of Regulation [European Health Data Space Regulation proposal] which are products with digital elements within the meaning of this Regulation should therefore also comply with the essential requirements set out in this Regulation. Their manufacturers should demonstrate conformity as required by Regulation [European Health Data Space Regulation proposal]. To facilitate compliance, manufacturers may draw up a single technical documentation containing the elements required by both legal acts. As this Regulation does not cover SaaS as such, EHR systems offered through the SaaS licensing and delivery model are not within the scope of this Regulation. Similarly, EHR systems that are developed and used in-house *do not fall* within the scope of this Regulation, as they are not placed on the market.
- (32) In order to ensure that products with digital elements are secure both at the time of their placing on the market as well as *during the time the product is expected to be in use*, it is necessary to lay down essential requirements for vulnerability handling and essential cybersecurity requirements relating to the properties of products with digital elements. While manufacturers should comply with all essential requirements related to vulnerability handling *throughout the support period*, they should determine which other essential requirements related to the product properties are relevant for the concerned type of product. For this purpose, manufacturers should undertake an assessment of the cybersecurity risks associated with a product with digital elements to identify relevant risks and relevant essential requirements and in order to *make available their products without known exploitable vulnerabilities that might have an impact on the security of those products and to* appropriately apply suitable harmonised standards, common specifications *or European or international standards*.

(32a) Where certain essential requirements are not applicable to a product with digital elements, the manufacturer should include a clear justification in the cybersecurity risk assessment included in the technical documentation. This could be the case where an essential requirement would be incompatible with the nature of a product with digital elements. For example, the intended purpose of a product may require the manufacturer to follow widely recognised interoperability standards even if their security features are no longer considered state of the art. Similarly, other Union legislation may require manufacturers to apply specific interoperability requirements. Where an essential requirement is not applicable to a product with digital elements, but the manufacturer has identified cybersecurity risks in relation to this essential requirement, it should take measures to address those risks by other means, for instance by limiting the intended purpose of the product to trusted environments or by informing the users about those risks.

- (32b)** *One of the most important measures for users to take in order to protect their products with digital elements from cyberattacks is to install the latest available security updates as soon as possible. Manufacturers should therefore design their products and create processes to ensure that products with digital elements include functions that enable the notification, distribution, download and installation of security updates automatically, in particular in the case of consumer products. They should also provide the possibility to approve the download and installation of the security updates as a final step. Users should retain the possibility to deactivate automatic updates, with a clear and easy-to-use mechanism, supported by clear instructions on how users can opt out. The requirements relating to automatic updates laid down in Annex I of this Regulation are not applicable to products primarily intended to be integrated as components into other products. They also do not apply to products with digital elements for which users would not reasonably expect automatic updates, including products with digital elements intended to be used in professional ICT-networks, and especially in critical and industrial environments where an automatic update could cause interference with operations. Irrespective of whether a product with digital elements is designed to receive automatic updates or not, its manufacturer should inform users about vulnerabilities and make security updates available without delay. Where the product with digital elements has a user interface or similar technical means allowing direct interaction with its users, the manufacturer should make use of such features to inform users that their product with digital elements has reached the end of the support period. Notifications should be limited to what is necessary in order to ensure the effective reception of this information and should not have a negative impact on the user experience of the product with digital elements.*
- (32c)** *To improve the transparency of vulnerability handling processes and to ensure that users are not required to install new functionality updates for the sole purpose of receiving the latest security updates, manufacturers should ensure, where technically feasible, that new security updates are provided separately from functionality updates.*

- (33) In order to improve the security of products with digital elements placed on the internal market it is necessary to lay down essential requirements. These essential requirements should be without prejudice to the **Union level** coordinated **security** risk assessments of critical supply chains established **pursuant to** Article 22 of Directive (EU) 2022/2555, which take into account both technical and, where relevant, non-technical risk factors, such as undue influence by a third country on suppliers. Furthermore, it should be without prejudice to the Member States' prerogatives to lay down additional requirements that take account of non-technical factors for the purpose of ensuring a high level of resilience, including those defined in Recommendation (EU) 2019/534, in the **EU** coordinated risk assessment of **the cybersecurity of 5G networks** and in the EU Toolbox on 5G cybersecurity agreed by the **Cooperation Group established under** Directive (EU) 2022/2555.
- (33a) *For the purpose of ensuring the security of products with digital elements after their placing on the market, manufacturers should determine the support period which should reflect the time the product is expected to be in use. In determining the support period, manufacturers should take into account in particular the reasonable user expectations, the nature of the product, as well as relevant Union law determining the lifetime of products with digital elements. They should also be able to take into account other relevant factors. The criteria should be applied in a manner that ensures proportionality in the determination of the support period. Upon request, manufacturers should provide market surveillance authorities with the information that was taken into account to determine the support period of a product with digital elements.*

- (33b) The support period for which the manufacturer guarantees the effective handling of vulnerabilities should be no less than five years, unless the lifetime of the product with digital elements is less than five years, in which case the manufacturer should ensure the vulnerability handling for that lifetime. Where the time the product is reasonably expected to be in use is longer than five years, as is often the case for hardware components such as motherboards or microprocessors, network devices such as routers, modems or switches, as well as software, such as operating systems or video-editing tools, manufacturers should accordingly guarantee longer support times. In particular products with digital elements intended for use in industrial settings, such as industrial control systems, often are in use for significantly longer periods of time. Manufacturers may define a support period of less than five years only where this is justified by the nature of the product and when the product with digital elements is expected to be in use for less than five years, in which case the support period should correspond to the expected use time. For instance, the lifetime of a contact tracing app intended for use during a pandemic could be limited to the length of the pandemic. Moreover, some software applications can by nature only be made available on the basis of a subscription model, in particular in cases where the application becomes unavailable to the user and consequently not in use anymore once the subscription expires.*
- (33c) When products with digital elements reach the end of their support period, in order to ensure that vulnerabilities can be handled even after the end of the support period, manufacturers should consider releasing the source code of such products with digital elements either to other undertakings which commit to extending the provision of vulnerability handling services or to the public. Where manufacturers release the source code to other undertakings, they should be able to protect the ownership of the product with digital elements and prevent the dissemination of the source code to the public, for example through contractual arrangements.*

- (33d) In order to ensure that manufacturers across the Union determine similar support periods for comparable products with digital elements, the administrative cooperation group (ADCO) established under this Regulation should publish relevant statistics on the average support periods determined by manufacturers for categories of products with digital elements and issue guidance indicating appropriate support periods for such categories. In addition, with a view to ensuring a harmonised approach across the internal market, the Commission should be able to adopt delegated acts to specify the minimum support period for specific product categories in cases where the data provided by market surveillance authorities suggests that the support periods determined by manufacturers are either systematically not in line with the criteria for determining the support periods as laid down in this Regulation or that manufacturers in different Member States unjustifiably determine different support periods.*
- (33e) Manufacturers should set up a single point of contact that enables users to communicate easily with them, including for the purposes of reporting on and receiving information about the cybersecurity vulnerabilities of the product with digital element. They should make the single point of contact easily accessible for users and clearly indicate its availability, keeping this information up to date. Where manufacturers choose to offer automated tools, e.g. through chat boxes, they should also offer a phone number or other digital means of contact, such as an email address or a contact form. The single point of contact should not rely exclusively on automated tools.*
- (33f) Manufacturers should make their products with digital elements available on the market with a secure by default configuration and provide security updates to users free of charge. Manufacturers should only be able to deviate from these essential requirements in relation to tailor-made products that are fitted to a particular purpose for a particular business user and where both the manufacturer and the user have explicitly agreed to a different set of contractual terms.*

(33g) The joint communication of the Commission and the High Representative of the Union for Foreign Affairs and Security Policy/Vice-President of the European Commission to the European Parliament, the European Council and the Council on “European Economic Security Strategy” stated that the Union needs to maximise the benefits of its economic openness while minimising the risks from economic dependencies on high-risk vendors, through a common strategic framework for Union economic security. Dependencies on high-risk suppliers of products with digital elements may pose a strategic risk that needs to be addressed at Union level, especially when the products with digital elements are intended for the use by essential entities of the type referred to in Directive (EU) 2022/2555. Such risks may be linked, but not limited, to the jurisdiction applicable to the manufacturer, the characteristics of its corporate ownership and the links of control to a third-country government where it is established, in particular whether a country engages in economic espionage or irresponsible state behaviour in cyberspace and its legislation obliges arbitrary access to any kind of company operations or data, including commercially sensitive data, and can impose obligations for intelligence purposes without democratic checks and balances, oversight mechanism, due process or the right to appeal to an independent judiciary. When determining the significance of a cybersecurity risk within the meaning of this Regulation, the Commission and the market surveillance authorities, as per their responsibilities set out in this Regulation, should also consider non-technical risk factors, in particular those established as a result of Union level coordinated security risk assessments of critical supply chains in accordance with Article 22 of Directive (EU) 2022/2555.

(33h) Manufacturers should notify simultaneously via the single reporting platform both the CSIRT designated as coordinator as well as ENISA of actively exploited vulnerabilities contained in products with digital elements, as well as severe incidents having an impact on the security of those products. The notifications should be submitted using the electronic notification end-point of a CSIRT designated as coordinator and should be simultaneously accessible to ENISA.

- (34) **Manufacturers should notify vulnerabilities that are actively exploited to ensure that the CSIRTs designated as coordinators, and ENISA, have an adequate overview of the vulnerabilities exploited and** are provided with the information necessary to fulfil their tasks **as set out in Directive (EU) 2022/2555** and raise the overall level of cybersecurity of essential and important entities, **as well as** to ensure the effective functioning of market surveillance authorities **■**. As most products with digital elements are marketed across the entire internal market, any exploited vulnerability in a product with digital elements should be considered a threat to the functioning of the internal market. **ENISA** should, **in agreement with the manufacturer, disclose** fixed vulnerabilities to the European vulnerability database established under Directive **(EU) 2022/2555**. **The European vulnerability database will assist the manufacturers in detecting known exploitable vulnerabilities in their products, in order to ensure that secure products are made available on the market.**
- (35) Manufacturers should also **notify** any **severe** incident having an impact on the security of the product with digital elements **to the CSIRT** designated **as coordinator and ENISA ■**. In order to ensure that users can react quickly to **severe** incidents having an impact on the security of their products with digital elements, manufacturers should also inform their users about any such incident and, where applicable, about any corrective measures that the users can deploy to mitigate the impact of the incident, for example by publishing relevant information on their websites or, where the manufacturer is able to contact the users and where justified by the risks, by reaching out to the users directly.

- (35a)** *Actively exploited vulnerabilities concern instances where a manufacturer establishes that a security breach affecting its users or any other natural or legal persons has resulted from a malicious actor making use of a flaw in one of the products with digital elements made available on the market by the manufacturer. Examples of such vulnerabilities could be weaknesses in a product’s identification and authentication functions. Vulnerabilities that are discovered with no malicious intent for purposes of good faith testing, investigation, correction or disclosure to promote the security or safety of the system owner and its users should not be subject to mandatory notifications. Severe incidents having an impact on the security of the product with digital elements, on the other hand, refer to situations where a cybersecurity incident affects the development, production or maintenance processes of the manufacturer in such a way that it could result in an increased cybersecurity risk for users or other persons. Such a severe incident could include a situation in which an attacker has successfully introduced malicious code into the release channel via which the manufacturer releases security updates to users.*
- (35b)** *To ensure that notifications can be disseminated quickly to all relevant CSIRTs designated as coordinators and to enable manufacturers to submit only one single notification at each stage of the notification process, a single reporting platform with national electronic notification end-points should be established, and the day-to-day operations of the platform should be managed and maintained by ENISA. Relevant CSIRTs designated as coordinator should inform their respective market surveillance authorities about the notified vulnerability or incident. The platform should be designed in such a way that it ensures the confidentiality of notifications with particular regard to vulnerabilities for which a security update is not yet available. In addition, ENISA should put in place procedures to handle information in a secure and confidential manner. On the basis of the information it gathers, ENISA should prepare a biennial technical report on emerging trends regarding cybersecurity risks in products with digital elements and submit it to the Cooperation Group referred to in Directive (EU) 2022/2555.*

(35c) In exceptional circumstances and in particular upon request by the manufacturer, the CSIRT designated as coordinator initially receiving a notification should be able to decide to delay its dissemination to the other relevant CSIRTs designated as coordinators via the single reporting platform where this can be justified on cybersecurity related grounds and for a period of time that is strictly necessary. The CSIRT should immediately inform ENISA about the decision to delay and on which grounds, as well as when it intends to disseminate further. The Commission should develop, through a delegated act, specifications on the terms and conditions for when cybersecurity related grounds could be applied and should cooperate with the CSIRTs network and ENISA in preparing this draft delegated act. Examples of cybersecurity related grounds include an ongoing coordinated vulnerability disclosure procedure or situations in which a manufacturer is expected to provide a mitigating measure shortly and the cybersecurity risks of an immediate dissemination via the platform outweigh its benefits. If requested by the CSIRT, ENISA may support the CSIRT on the application of cybersecurity related grounds in relation to delaying the dissemination of the notification based on the information they should receive from the CSIRT on the decision to withhold a notification on those cybersecurity grounds. Furthermore, in particularly exceptional circumstances, ENISA should not receive all the details of a notification of an actively exploited vulnerability in a simultaneous manner. This would be the case when the manufacturer marks in its notification that the notified vulnerability has been actively exploited by a malicious actor and that, according to the information available, it has been exploited in no other Member State than the one of the CSIRT to which the manufacturer has notified the vulnerability, or when any immediate further dissemination of the notified vulnerability would likely result in the supply of information the disclosure of which would be contrary to the essential interests of that Member State, or when the notified vulnerability poses an imminent high cybersecurity risk stemming from the further dissemination. In such cases, ENISA will only receive simultaneous access to the information that a notification was made by the manufacturer, general information about the product, general nature of the exploit and information on the fact that these security grounds were raised by the manufacturer and hence that the full content of the notification is withheld.

The full notification should then be available to ENISA and other relevant CSIRTs designated as coordinators when the CSIRT initially receiving the notification finds that these security grounds, reflecting particularly exceptional circumstances as established by this Regulation, cease to exist. Where, based on the information available ENISA considers that there is a systemic risk affecting the security of the internal market, ENISA should recommend to the recipient CSIRT to disseminate the full notification to the other CSIRTs and itself.

(35d) When manufacturers notify an actively exploited vulnerability or a severe incident having an impact on the security of the product with digital elements, they should indicate how sensitive they deem the notified information to be. The CSIRT designated as coordinator initially receiving the notification should take this information into account when assessing whether the notification gives rise to exceptional circumstances that justify a delay in the dissemination of the notification to the other relevant CSIRTs based on justified cybersecurity related grounds. It should also take this information into account when assessing whether the notification of an actively exploited vulnerability gives rise to particularly exceptional circumstances that justify that the full notification is not made available simultaneously to ENISA. Finally, CSIRTs should be able to take this information into account when determining appropriate measures to mitigate the risks stemming from such vulnerabilities and incidents.

(35e) Considering its expertise and mandate, ENISA should be able to support the process for implementation of this Regulation. In particular, it should be able to propose joint activities to be conducted by market surveillance authorities based on indications or information regarding potential non-compliance with this Regulation of products with digital elements across several Member States or identify categories of products for which simultaneous coordinated control actions should be organised. In exceptional circumstances, at the request of the Commission, ENISA should be able to conduct evaluations in respect of specific products with digital elements that present a significant cybersecurity risk, where an immediate intervention is required to preserve the good functioning of the internal market.

- (35f)** *In order to simplify the reporting of information required under this Regulation, in consideration of other complementary reporting requirements laid down in other Union law, such as Regulation (EU) 2022/2554, Directive (EU) 2022/2555, Regulation (EU) 2016/679 and Directive 2002/58/EC, as well as in order to decrease the administrative burden for entities, Member States are encouraged to consider providing at national level single entry points for such reporting requirements. The use of such national single entry points for the reporting of security incidents under Regulation (EU) 2016/679 and Directive 2002/58/EC should not affect the application of the provisions of Regulation (EU) 2016/679 and Directive 2002/58/EC, in particular those relating to the independence of the authorities referred to therein. When establishing the single reporting platform referred in this Regulation, ENISA should also take into account the possibility for the national electronic notification end-points referred to in this Regulation to be integrated into national single entry points that may also integrate other notifications required by other Union law.*
- (35g)** *When establishing the single reporting platform referred in this Regulation and in order to benefit from past experience, ENISA should also consult other Union institutions or agencies that are managing platforms or databases subject to stringent security requirements, such as the European Union Agency for the Operational Management of Large-Scale IT Systems in the Area of Freedom, Security and Justice (eu-LISA). ENISA should also analyse potential complementarities with the European vulnerability database established in accordance with Article 12(2) of Directive (EU) 2022/2555.*
- (35h)** *Manufacturers and other entities and actors should also be able to report to a CSIRT designated as coordinator or ENISA, on a voluntary basis, about other cybersecurity incidents, cyber threats that could affect the risk profile of the product with digital elements, near misses that could have resulted in an incident having an impact on the security of the product with digital elements and any other vulnerability.*

- (35i) *Member States should aim to address, to the extent possible, the challenges faced by vulnerability researchers, including their potential exposure to criminal liability, in accordance with national law. Given that natural and legal persons researching vulnerabilities could in some Member States be exposed to criminal and civil liability, Member States are encouraged to adopt guidelines as regards the non-prosecution of information security researchers and an exemption from civil liability for their activities.*
- (36) Manufacturers of products with digital elements should put in place coordinated vulnerability disclosure policies to facilitate the reporting of vulnerabilities by individuals or entities *either directly to the manufacturer or indirectly, and where requested anonymously, via CSIRTs designated as a coordinator for the purposes of coordinated vulnerability disclosure in accordance with Article 12(1) of Directive (EU) 2022/2555.* *Manufacturers’* coordinated vulnerability disclosure policy should specify a structured process through which vulnerabilities are reported to a manufacturer in a manner allowing the manufacturer to diagnose and remedy such vulnerabilities before detailed vulnerability information is disclosed to third parties or to the public. *Moreover, manufacturers should also consider publishing their security policies in machine-readable format.* Given the fact that information about exploitable vulnerabilities in widely used products with digital elements can be sold at high prices on the black market, manufacturers of such products should be able to use programmes, as part of their coordinated vulnerability disclosure policies, to incentivise the reporting of vulnerabilities by ensuring that individuals or entities receive recognition and compensation for their efforts (so-called ‘bug bounty programmes’).
- (37) In order to facilitate vulnerability analysis, manufacturers should identify and document components contained in the products with digital elements, including by drawing up a software bill of materials (*SBOMs*). *A SBOM* can provide those who manufacture, purchase, and operate software with information that enhances their understanding of the supply chain, which has multiple benefits, most notably it helps manufacturers and users to track known newly emerged vulnerabilities and risks. It is of particular importance for manufacturers to ensure that their products do not contain vulnerable components developed by third parties. *Manufacturer should not, however, be obliged to make the software bill of materials public.*

(37a) Under the new complex business models linked to online sales, a business operating online can provide a variety of services. Depending on the nature of the services provided in relation to a given product with digital elements, the same entity may fall within different categories of business models or economic operators. Where an entity provides only online intermediation services for a given product with digital elements and is merely a provider of an online marketplace, as defined by Article 3, point (14), of Regulation (EU) 2023/988²⁰, it does not qualify as one of the types of economic operator defined in this Regulation. Where the same entity is a provider of an online marketplace and also acts as an economic operator as defined in this Regulation for the sale of particular products with digital elements, it should be subject to the obligations set out by this Regulation for that type of economic operator. For instance, if the provider of the online marketplace also distributes a product with digital elements, then, with respect to the sale of that product, it would be considered to be a distributor. Similarly, if the entity in question sells its own branded products with digital elements, it would qualify as a manufacturer and would thus have to comply with the applicable requirements for manufacturers. Also, some entities can qualify as fulfilment service providers as defined by Article 3(11) of Regulation (EU) 2019/1020 if they offer such services. Such cases would need to be assessed on a case-by-case basis. Given the prominent role that online marketplaces have in enabling electronic commerce, they should strive to cooperate with the market surveillance authorities of the Member States in order to help ensure that products purchased through online marketplaces comply with the cybersecurity requirements laid down in this Regulation.

²⁰ **Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1).**

- (38) In order to facilitate assessment of conformity with the requirements laid down by this Regulation, there should be a presumption of conformity for products with digital elements which are in conformity with harmonised standards, which translate the essential requirements of this Regulation into detailed technical specifications, and which are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council²¹. Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation. ***The standardisation process should ensure a balanced representation of interests and effective participation of civil society stakeholders, including consumer organisations. International standards that are in line with the level of cybersecurity protection aimed for by the essential requirements set out in this Regulation should also be taken into account, in order to facilitate the development of harmonised standards and the implementation of this Regulation, as well as to ease compliance for companies, in particular micro, small and medium-sized companies and those operating globally.***
- (38a) ***The timely development of harmonised standards during the transition period and their availability before the date of application of this Regulation will be particularly important for an effective implementation. This is notably the case for important products with digital elements that fall under class I. The availability of harmonised standards will enable manufacturers of such products to perform the conformity assessments via the internal control procedure and therefore can avoid bottlenecks and delays with the activities of conformity assessment bodies.***

²¹ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

(39) Regulation (EU) 2019/881 establishes a voluntary European cybersecurity certification framework for ICT products, processes and services. European cybersecurity certification schemes *provide a common framework of trust for users to use* products with digital elements covered by this Regulation. This Regulation should *consequently* create synergies with Regulation (EU) 2019/881. In order to facilitate the assessment of conformity with the requirements laid down in this Regulation, products with digital elements that are certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 and which has been identified by the Commission in an implementing act, shall be presumed to be in compliance with the essential requirements of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements. The need for new European cybersecurity certification schemes for products with digital elements should be assessed in the light of this Regulation, *including when preparing the Union rolling work programme in line with Regulation (EU) 2019/881. Where there is a need for a new scheme covering products with digital elements, including in order to facilitate the compliance with this Regulation, the Commission may request ENISA to prepare candidate schemes in accordance with Article 48 of Regulation (EU) 2019/881.* Such future European cybersecurity certification schemes covering products with digital elements should take into account the essential requirements *and conformity assessment procedures* as set out in this Regulation and facilitate compliance with this Regulation. *For the European cybersecurity certification schemes that enter into force before the entry into force of this Regulation, further specifications may be needed on detailed aspects of how a presumption of conformity can apply* The Commission should be empowered to specify, by means of *delegated acts, under which conditions* the European cybersecurity certification schemes ■ can be used to demonstrate conformity with the essential requirements set out in this Regulation. Furthermore, ■ to avoid undue administrative burden, *there should be no* obligation for manufacturers to carry out a third-party conformity assessment as provided by this Regulation for corresponding requirements *where a cybersecurity certificate has been issued under such European cybersecurity certification schemes at least at level substantial.*

- (40) Upon entry into force of the implementing act setting out the [Commission Implementing Regulation (EU) No .../... of XXX on the European Common Criteria-based cybersecurity certification scheme] (EUCC) which concerns █ products covered by this Regulation, such as hardware security modules and microprocessors, the Commission may specify, by means of a delegated act, how the EUCC provides a presumption of conformity with the essential requirements as referred to in Annex I of this Regulation or parts thereof. Furthermore, such a delegated act may specify how a certificate issued under the EUCC eliminates the obligation for manufacturers to carry out a third-party assessment as requested by this Regulation for corresponding requirements.
- (41) *The current EU standardisation framework which is based on the New Approach principles set out in Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards and on Regulation (EU) No 1025/2012 represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential requirements of this Regulation. European standards should be market-driven, take into account the public interest, as well as the policy objectives clearly stated in the Commission’s request to one or more European standardisation organisations to draft harmonised standards, within a set deadline and be based on consensus. However, in the absence of relevant references to harmonised standards, the Commission should be able to adopt implementing acts establishing common specifications for the essential cybersecurity requirements of this Regulation, provided that in doing so it duly respects the role and functions of standardisation organisations, as an exceptional fall back solution to facilitate the manufacturer’s obligation to comply with those cybersecurity requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards. If such delay is due to the technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications.*
- (41a) *With a view to establishing, in the most efficient way, common specifications that cover the essential requirements of this Regulation, the Commission should involve relevant stakeholders in the process.*

- (41b)** *Reasonable period should mean, in relation to the publication of reference to harmonised standards in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, a period during which the publication in the Official Journal of the European Union of the reference to the standard, its corrigendum or its amendment is expected and which should not exceed one year after the deadline for drafting a European standard set in accordance with Regulation (EU) No 1025/2012.*
- (41c)** *In order to facilitate assessment of conformity with the essential requirements laid down by this Regulation, there should be a presumption of conformity for products with digital elements that are in conformity with the common specifications adopted by the Commission according to this Regulation for the purpose of expressing detailed technical specifications of those requirements.*
- (41d)** *The application of harmonised standards, common specifications or cybersecurity certification schemes under Regulation (EU) 2019/881 providing presumption of conformity in relation to the essential requirements applicable to the products with digital elements will facilitate the assessment of conformity by the manufacturer. If the manufacturer chooses not to apply such means for certain requirements, they have to indicate in their technical documentation how the compliance is reached otherwise. Furthermore, the application of harmonised standards, common specifications or cybersecurity certification schemes under Regulation (EU) 2019/881 providing presumption of conformity by manufacturers would facilitate the check of compliance of products with digital elements by market surveillance authorities. Therefore, manufacturers of products with digital elements are encouraged to apply harmonised standards, common specifications or cybersecurity certification schemes under Regulation (EU) 2019/881 providing presumption of conformity to demonstrate conformity with the essential requirements of this Regulation.*

- (42) Manufacturers should draw up an EU declaration of conformity to provide information required under this Regulation on the conformity of products with digital elements with the essential requirements of this Regulation and, where applicable, of the other relevant Union harmonisation legislation by which the product is covered. Manufacturers may also be required to draw up an EU declaration of conformity by other Union legislation. To ensure effective access to information for market surveillance purposes, a single EU declaration of conformity should be drawn up in respect of compliance with all relevant Union acts. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.
- (43) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008 of the European Parliament and of the Council²². Rules governing the affixing of the CE marking on products with digital elements should be laid down in this Regulation. The CE marking should be the only marking which guarantees that products with digital elements comply with the requirements of this Regulation.

²² Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

(44) In order to allow economic operators to demonstrate conformity with the essential requirements laid down in this Regulation and to allow market surveillance authorities to ensure that products with digital elements made available on the market comply with these requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC of the European Parliament and of the Council²³ establishes modules for conformity assessment procedures in proportion to the level of risk involved and the level of security required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures adequate for verifying the conformity of products with digital elements with the essential requirements set out in this Regulation have been based on those modules. The conformity assessment procedures should examine and verify both product and process-related requirements covering the *time the products with digital elements are expected to be in use*, including planning, design, development or production, testing and maintenance of the product.

²³ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

- (45) **■** Conformity assessment of products with digital elements *that are not covered by Annex III or IIIa of this Regulation can* be carried out by the manufacturer under its own responsibility following the *internal control* procedure based on Module A of Decision 768/2008/EC *as set out in Annex VI of this Regulation. This also applies to cases where a manufacturer chooses to not apply in whole or in part an applicable harmonised standard, common specification or European cybersecurity certification.* The manufacturer *retains* flexibility to choose a stricter conformity assessment procedure involving a third-party. *Under the internal control conformity assessment procedure, the manufacturer ensures and declares on its sole responsibility that the product with digital elements meets all the applicable essential requirements set out in Section 1 of Annex I of this Regulation and that the processes of the manufacturer meet the essential requirements set out in Section 2 of Annex I of this Regulation. If the important product belongs* to class I, additional assurance is required to demonstrate conformity with the essential requirements set out in this Regulation. The manufacturer should apply harmonised standards, common specifications or cybersecurity certification schemes under Regulation (EU) 2019/881, if it wants to carry out the conformity assessment under its own responsibility (module A). If the manufacturer does not apply such harmonised standards, common specifications or *European* cybersecurity certification schemes, the manufacturer should undergo conformity assessment involving a third party *(based on Modules B and C or H)*. Taking into account the administrative burden on manufacturers and the fact that cybersecurity plays an important role in the design and development phase of tangible and intangible products with digital elements, conformity assessment procedures respectively based on modules B+C or module H of Decision 768/2008/EC have been chosen as most appropriate for assessing the compliance of *important* products with digital elements, in a proportionate and effective manner. The manufacturer that carries out the third-party conformity assessment can choose the procedure that suits best its design and production process. Given the even greater cybersecurity risk linked with the use of *important* products *of class II ■*, the conformity assessment should always involve a third party, *even where the product complies fully or partly with harmonised standards, common specifications or European cybersecurity certification. Manufacturers of important products with digital elements qualifying as free and open-source software should be able to follow the internal control procedure based on Module A provided that they make the technical documentation available to the public.*

(46) While the creation of tangible products with digital elements usually requires manufacturers to make substantial efforts throughout the design, development and production phases, the creation of products with digital elements in the form of software almost exclusively focuses on design and development, while the production phase plays a minor role. Nonetheless, in many cases software products still need to be compiled, built, packaged, made available for download or copied onto physical media before being placed on the market. These activities should be considered as activities amounting to production when applying the relevant conformity assessment modules to verify the compliance of the product with the essential requirements of this Regulation across the design, development and production phases.

(46a) In relation to small and micro enterprises, in order to ensure proportionality, it is appropriate to alleviate administrative costs without affecting the level of cybersecurity protection of products with digital elements under the scope of this Regulation or the level playing field among manufacturers. Therefore, it is appropriate for the Commission to establish a simplified technical documentation form targeted at the needs of small and micro enterprises. The simplified technical documentation form adopted by the Commission should cover all the elements listed in Annex V and specify how a micro or small enterprise can provide the requested elements in a concise way, such as the description of the design, development and production of the product with digital elements. In doing so, the form would contribute to alleviating the administrative compliance burden by providing the concerned enterprises with legal certainty about the length and detail of information to be provided. Micro and small enterprises may choose to provide the elements listed in Annex V in extensive form and not take advantage of the simplified technical form available to them.

- (46b) In order to promote and protect innovation, it is important that the interests of SME manufactures, in particular small and micro enterprises, including start-ups, are taken into particular account. To this objective, Member States could develop initiatives which are targeted at small and micro manufacturers, including on training, awareness raising, information communication and on testing and third-party conformity assessment activities, as well as the establishment of sandboxes. Translation costs related to mandatory documentation, such as the technical documentation and the information and instructions for the user as required by this Regulation, and communication with authorities may constitute a significant cost for manufacturers, notably those of a smaller scale. Therefore, Member States may consider that one of the languages determined and accepted by them for relevant manufacturers' documentation and for communication with manufacturer is one which is broadly understood by the largest possible number of users.*
- (46c) In order to ensure a smooth application of this Regulation, Member States should strive to ensure, before the date of application of this Regulation, that a sufficient number of notified bodies is available to carry out third-party conformity assessments. The Commission should seek to assist Member States and other relevant parties in this endeavour, in order to avoid bottlenecks and hindrances to market entry for manufacturers. Targeted training activities led by Member States, including where appropriate with the support of the Commission, can contribute to the availability of skilled professionals including to support the activities of notified bodies under this Regulation. Furthermore, considering the costs that third-party conformity assessment may entail, funding initiatives at Union level and national level that seek to alleviate such costs for micro and small enterprises should be considered.*
- (46d) In order to ensure proportionality, conformity assessment bodies, when setting the fees for conformity assessment procedures, should take into account the specific interests and needs of micro, small and medium-sized enterprises, including start-ups. In particular, conformity assessment bodies should apply the examinations and tests defined in points 4.3, 4.4 and 4.5 of the EU-type examination procedure set out in Annex VI to this Regulation only where appropriate following a risk-based approach.*

- (46e) Micro, small and medium-sized enterprises or ‘SMEs’ referred to in this Regulation mean micro, small and medium-sized enterprises as defined in the Annex to Recommendation 2003/361/EC. When determining the category an enterprise falls into, the provisions of that Annex should be applied in their entirety. Therefore, when calculating the staff headcount and financial ceilings determining the enterprise categories, the provisions of Article 6 of the Annex to Recommendation 2003/361/EC on establishing the data of an enterprise in consideration of specific types of enterprises, such as partner enterprises or linked enterprises, should also apply.***
- (46f) The objectives of regulatory sandbox should be to foster innovation and competitiveness for businesses by establishing controlled testing environments before the placing on the market of products with digital elements. Regulatory sandboxes should contribute to improve legal certainty for all actors covered by this Regulation and facilitate and accelerate access to the Union market for products with digital elements, in particular when provided by small and micro enterprises, including start-ups.***
- (47) In order to carry out third-party conformity assessment for products with digital elements, conformity assessment bodies should be notified by the national notifying authorities to the Commission and the other Member States, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests.
- (48) In order to ensure a consistent level of quality in the performance of conformity assessment of products with digital elements, it is also necessary to lay down requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies. The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

- (48a) *Conformity assessment bodies that have been accredited and notified under Union legislation laying down similar requirements, such as a conformity assessment body that has been notified for a European cybersecurity certification scheme adopted as per Regulation (EU) 2019/881 or notified under the Delegated Regulation (EU) 2022/30, should be newly assessed and notified under this Regulation. However, synergies can be defined by relevant authorities regarding any overlapping requirements in order to prevent an unnecessary financial and administrative burden and ensure a smooth and timely notification process.***
- (49) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (50) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the product with digital elements to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks.
- (51) The notification of a conformity assessment body should be sent by the notifying authority to the Commission and the other Member States via the New Approach Notified and Designated Organisations (NANDO) information system. NANDO is the electronic notification tool developed and managed by the Commission where a list of all notified bodies can be found.

- (52) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (53) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burden for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That should be best achieved through appropriate coordination and cooperation between notified bodies.
- (54) Market surveillance is an essential instrument in ensuring the proper and uniform application of Union legislation. It is therefore appropriate to put in place a legal framework within which market surveillance can be carried out in an appropriate manner. Rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EU) 2019/1020 of the European Parliament and of the Council²⁴ apply to products with digital elements covered by this Regulation.

²⁴ Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

(55) In accordance with Regulation (EU) 2019/1020, market surveillance authorities carry out market surveillance in the territory of that Member State. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks. Each Member State should designate one or more market surveillance authorities in its territory. Member States may choose to designate any existing or new authority to act as market surveillance authority, including ■ competent authorities *established pursuant to Article 8 of Directive (EU) 2022/2555* or designated national cybersecurity certification authorities referred to in Article 58 of Regulation (EU) 2019/881 *or market surveillance authorities designated for the purpose of Directive 2014/53/EU*. Economic operators should fully cooperate with market surveillance authorities and other competent authorities. Each Member State should inform the Commission and the other Member States of its market surveillance authorities and the areas of competence of each of those authorities and should ensure the necessary resources and skills to carry out the surveillance tasks relating to this Regulation. As per Article 10(2) and (3) of Regulation (EU) 2019/1020, each Member State should appoint a single liaison office that should be responsible, among others, for representing the coordinated position of the market surveillance authorities and assisting in the cooperation between market surveillance authorities in different Member States.

- (56) A dedicated administrative cooperation group (ADCO) *for the cyber resilience of products with digital elements* should be established for the uniform application of this Regulation, pursuant to Article 30(2) of Regulation (EU) 2019/1020. This ADCO should be composed of representatives of the designated market surveillance authorities and, if appropriate, representatives of the single liaison offices. The Commission should support and encourage cooperation between market surveillance authorities through the Union Product Compliance Network, established on the basis of Article 29 of Regulation (EU) 2019/1020 and comprising representatives from each Member State, including a representative of each single liaison office referred to in Article 10 of Regulation (EU) 2019/1020 and an optional national expert, the chairs of ADCOs, and representatives from the Commission. The Commission should participate in the meetings of the Network, its sub-groups and this respective ADCO. It should also assist this ADCO by means of an executive secretariat that provides technical and logistic support. *ADCO may also invite independent experts to participate, and liaise with other ADCOs, such as the one established under Directive 2014/53/EU.*
- (56a) *Market surveillance authorities, through the ADCO established under this Regulation, should cooperate closely and should be able to develop guidance documents to facilitate market surveillance activities at national level, such as by developing best practices and indicators to effectively check the compliance of products with digital elements.*
- (57) In order to ensure timely, proportionate and effective measures in relation to products with digital elements presenting a significant cybersecurity risk, a Union safeguard procedure should be *provided* under which interested parties are informed of measures intended to be taken with regard to such products. This should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage where necessary. Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(58) In certain cases, a product with digital elements which complies with this Regulation, may nonetheless present a significant cybersecurity risk or pose a risk to the health or safety of persons, to compliance with obligations under Union or national law intended to protect fundamental rights, the availability, authenticity, integrity or confidentiality of services offered using an electronic information system by essential entities of the type referred to in **Article 1(2)** Directive *(EU) 2022/0255* or to other aspects of public interest protection. Therefore it is necessary to establish rules which ensure mitigation of those risks. As a result, market surveillance authorities should take measures to require the economic operator to ensure that the product no longer presents that risk, to recall it or to withdraw it, depending on the risk. As soon as a market surveillance authority restricts or forbids the free movement of a product in such way, the Member State should notify without delay the Commission and the other Member States of the provisional measures, indicating the reasons and justification for the decision. Where a market surveillance authority adopts such measures against products presenting a risk, the Commission should enter into consultation with the Member States and the relevant economic operator or operators without delay and should evaluate the national measure. On the basis of the results of this evaluation, the Commission should decide whether the national measure is justified or not. The Commission should address its decision to all Member States and immediately communicate it to them and the relevant economic operator or operators. If the measure is considered justified, the Commission may also consider adopting proposals to revise the respective Union legislation.

- (59) For products with digital elements presenting a significant cybersecurity risk, and where there is reason to believe that these are not compliant with this Regulation, or for products that are compliant with this Regulation, but that present other important risks, such as risks to the health or safety of persons, fundamental rights or the provision of the services by essential entities of the type referred to in **■** Directive **(EU) 2022/0255**, the Commission may request ENISA to carry out an evaluation. Based on that evaluation, the Commission may adopt, through implementing acts, corrective or restrictive measures at Union level, including ordering withdrawal from the market, or recalling of the respective products, within a reasonable period, commensurate with the nature of the risk. The Commission may have recourse to such intervention only in exceptional circumstances that justify an immediate intervention to preserve the good functioning of the internal market, and only where no effective measures have been taken by surveillance authorities to remedy the situation. Such exceptional circumstances may be emergency situations where, for example, a non-compliant product is widely made available by the manufacturer throughout several Member States, used also in key sectors by entities *that fall within* the scope of **■** Directive **(EU) 2022/0255** while containing known vulnerabilities that are being exploited by malicious actors and for which the manufacturer does not provide available patches. The Commission may intervene in such emergency situations only for the duration of the exceptional circumstances and if the non-compliance with this Regulation or the important risks presented persist.
- (60) In cases where there are indications of non-compliance with this Regulation in several Member States, market surveillance authorities should be able to carry out joint activities with other authorities, with a view to verifying compliance and identifying cybersecurity risks of products with digital elements.

- (61) Simultaneous coordinated control actions (‘sweeps’) are specific enforcement actions by market surveillance authorities that can further enhance product security. Sweeps should, in particular, be conducted where market trends, consumer complaints or other indications suggest that certain product categories are often found to present cybersecurity risks.
- Furthermore, when determining the product categories to be subjected to sweeps, market surveillance authorities should also take into account considerations relating to non-technical risk factors. To this end, market surveillance authorities may take into account the results of Union level coordinated security risk assessments of critical supply chains in accordance with Article 22 of Directive (EU) 2022/2555, including considerations relating to non-technical risk factors.*** ENISA should submit proposals for categories of products for which sweeps could be organised to the market surveillance authorities, based, among others, on the notifications of product vulnerabilities and incidents it receives.

(62) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 of the Treaty *on the Functioning of the European Union* should be delegated to the Commission in respect of updates to the list of *important* products *with digital elements* in Annex III **■** . Power to adopt acts in accordance with that Article should be delegated to the Commission to identify products with digital elements covered by other Union rules which achieve the same level of protection as this Regulation, specifying whether a limitation or exclusion from the scope of this Regulation would be necessary as well as the scope of that limitation, if applicable. Power to adopt acts in accordance with that Article should also be delegated to the Commission in respect of the potential mandating of certification *under a European cybersecurity certification scheme of the critical products with digital elements listed in Annex IIIa, as well as for updating the list of critical products with digital elements in that Annex* based on criticality *criteria set out in this Regulation and also for specifying the European cybersecurity certification schemes adopted pursuant to Regulation (EU) 2019/881 that can be used to demonstrate conformity with the essential requirements or parts thereof* as set out in *Annex I* to this Regulation. *Power to adopt delegated acts should also be conferred to the Commission to specify the minimum support period for specific product categories where the market surveillance data suggests inadequate support periods, as well as to specify the terms and conditions for applying the cybersecurity related grounds in relation to delaying the dissemination of notifications of actively exploited vulnerabilities. Furthermore, power to adopt delegated acts should also be conferred to the Commission to establish voluntary security attestation programmes for assessing the conformity of products with digital elements qualifying as free and open-source software with all or certain essential requirements or other obligations laid down in this Regulation, as well as to specify* the minimum content of the EU declaration of conformity and *to supplement* the elements to be included in the technical documentation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the *Interinstitutional* Agreement of 13 April 2016 on Better Law-Making²⁵.

²⁵ OJ L 123, 12.5.2016, p. 1.

In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. ***The power to adopt delegated acts conferred to the Commission by this Regulation is conferred for a period of five years from ... [date of entry into force of this Regulation]. The Commission should draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power should be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

- (63) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to: specify the ***technical description of the categories of products with digital elements listed in Annex III, specify the format and elements of the software bill of materials, specify further the*** ■, format and procedure of the notifications on actively exploited vulnerabilities and ***severe incidents having an impact on the security of products with digital elements submitted by the manufacturers, establish common specifications covering technical requirements that provide a means to comply*** with the essential requirements ■ set out in Annex I to this Regulation, ■ lay down technical specifications for ***labels, pictograms or any other marks related to the security of the products with digital elements, their support period and mechanisms to promote their use and to increase public awareness about the security of products with digital elements, specify the simplified documentation form targeted at the needs of micro and small enterprises,*** decide on corrective or restrictive measures at Union level in exceptional circumstances which justify an immediate intervention to preserve the good functioning of the internal market. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²⁶.

²⁶ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).

- (64) In order to ensure trustful and constructive cooperation of market surveillance authorities at Union and national level, all parties involved in the application of this Regulation should respect the confidentiality of information and data obtained in carrying out their tasks.
- (65) In order to ensure effective enforcement of the obligations laid down in this Regulation, each market surveillance authority should have the power to impose or request the imposition of administrative fines. Maximum levels for administrative fines to be provided for in national laws for non-compliance with the obligations laid down in this Regulation should therefore be established. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation should be taken into account and as a minimum those explicitly established in this Regulation ***the manufacturer is a microenterprise, a small or medium-sized enterprise, including a start-up or***, including whether administrative fines have been already applied by other market surveillance authorities to the same operator for similar infringements. Such circumstances can be either aggravating, in situations where the infringement by the same operator persists on the territory of other Member States than the one where an administrative fine has already been applied, or mitigating, in ensuring that any other administrative fine considered by another market surveillance authority for the same economic operator or the same type of breach should already take account, along with other relevant specific circumstances, of a penalty and the quantum thereof imposed in other Member States. In all such cases, the cumulative administrative fine that could be applied by market surveillance authorities of several Member States to the same economic operator for the same type of infringement should ensure the respect of the principle of proportionality. ***Given that administrative fines do not apply to microenterprises and small enterprises for failures to meet the 24-hour deadline for the early warning notification nor to open-source software stewards for any infringement to this Regulation, and subject to the principle that penalties should be effective, proportionate and dissuasive, Member States should not impose other kinds of penalties with pecuniary character on these entities.***

- (66) Where administrative fines are imposed on persons that are not an undertaking, the competent authority should take account of the general level of income in the Member State as well as the economic situation of the person when considering the appropriate amount of the fine. It should be for the Member States to determine whether and to what extent public authorities should be subject to administrative fines.
- (66a) Member States should examine, taking into account national circumstances, the possibility of using the revenues from the penalties as provided for in this Regulation or their financial equivalent to support cybersecurity policies and increase the level of cybersecurity in the Union by, inter alia, increasing the number of qualified cybersecurity professionals, strengthening capacity building for micro, small and medium-sized enterprises and improving public awareness of cyber threats.***
- (67) In its relationships with third countries, the EU endeavours to promote international trade in regulated products. A broad variety of measures can be applied in order to facilitate trade, including several legal instruments such as bilateral (inter-governmental) Mutual Recognition Agreements (MRAs) for conformity assessment and marking of regulated products. MRAs are established between the Union and third countries, which are on a comparable level of technical development and have a compatible approach concerning conformity assessment. These agreements are based on the mutual acceptance of certificates, marks of conformity and test reports issued by the conformity assessment bodies of either party in conformity with the legislation of the other party. Currently MRAs are in place for several countries. The agreements are concluded in a number of specific sectors, which might vary from one country to another. In order to further facilitate trade, and recognising that supply chains of products with digital elements are global, MRAs concerning conformity assessment may be concluded for products regulated under this Regulation by the Union in accordance with Article 218 TFEU. Cooperation with partner countries is also important, in order to strengthen cyber resilience globally, as in the long term this will contribute to a strengthened cybersecurity framework both within and outside of the EU.

- (67a) *Consumers should be entitled to enforce their rights in relation to the obligations imposed on economic operators under this Regulation through representative actions in accordance with Directive (EU) 2020/1828 of the European Parliament and of the Council²⁷. For that purpose, this Regulation should provide that Directive (EU) 2020/1828 is applicable to the representative actions concerning infringements of this Regulation that harm or can harm the collective interests of consumers. Annex I to that Directive should therefore be amended accordingly. It is for the Member States to ensure that that amendment is reflected in their transposition measures adopted in accordance with that Directive, although the adoption of national transposition measures in that regard is not a condition for the applicability of that Directive to those representative actions. The applicability of that Directive to the representative actions brought against infringements by economic operators of provisions of this Regulation that harm or can harm the collective interests of consumers should start from the date of application of this Regulation.*
- (68) The Commission should periodically review this Regulation, in consultation with *relevant stakeholders*, in particular with a view to determining the need for modification in the light of changes to societal, political, technological or market conditions. *This Regulation will facilitate the compliance with supply chain security obligations of entities falling within the scope of Directive (EU) 2022/2555 and Regulation (EU) 2022/2554 that use products with digital elements. The Commission should evaluate, as part of the periodical review of this Regulation, the combined effects of the Union cybersecurity framework in this regard.*
- (69) Economic operators should be provided with a sufficient time to adapt to the requirements of this Regulation. This Regulation should apply ... [36 months *from the date of its entry into force*], with the exception of the reporting obligations concerning actively exploited vulnerabilities and *severe incidents having an impact on the security of products with digital element*, which should apply... [21 months *from the date of entry into force of this Regulation*] and of the provisions on notification of conformity assessment bodies, which should apply ... [18 months] from the *date of entry into force of this Regulation*].

²⁷ *Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).*

- (69a) *It is important to provide support to micro, small and medium-sized enterprises, including start-ups, in the implementation of this Regulation and to minimise the risks to implementation resulting from lack of knowledge and expertise in the market, as well as in order to facilitate compliance of manufacturers with their obligations laid down in this Regulation. The Digital Europe Programme and other relevant Union programmes provide financial and technical support that enable these enterprises to contribute to the growth of the European economy and to strengthening the common level of cybersecurity in the EU. The European Cybersecurity Competence Center and National Coordination Centres as well as European Digital Innovation Hubs established by the Commission and the Member States at national or EU level can also support companies and public sector organisations and may contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide technical and scientific support to micro, small and medium sized enterprises, such as for testing activities and third-party conformity assessment. They can also foster the deployment of tools to facilitate the implementation of this Regulation.***
- (69b) *Furthermore, Member States should consider complementary actions aiming at providing guidance and support for microenterprises and for small and medium-sized enterprises, such as the establishment of regulatory sandboxes and dedicated channels for communication. In order to strengthen the level of cybersecurity within the Union, Member States may also provide support to develop capacity and skills related to cybersecurity of products with digital elements, improving economic operators' cyber resilience, in particular of microenterprises and of small and medium-sized enterprises and fostering public awareness about the cybersecurity of products with digital elements.***
- (70)** Since the objective of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(71) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council²⁸ and delivered *an* opinion on **9 November 2022**²⁹.

(71a) This Regulation confers certain tasks to ENISA which require appropriate resources in terms of both expertise and human resources in order to enable ENISA to effectively carry out the tasks under this Regulation. The Commission will propose the necessary budgetary resources for ENISA’s establishment plan, in accordance with the procedure set out in Article 29 of Regulation (EU) 2019/881 when preparing the draft general budget of the Union. In this process, the Commission considers the overall resources to enable ENISA to fulfil its tasks, including those conferred on ENISA with this Regulation,

²⁸ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

²⁹ ***OJ C 452, 29.11.2022, p. 23.***

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1
Subject matter

This Regulation lays down:

- (a) rules for the ***making available*** on the market of products with digital elements to ensure the cybersecurity of such products;
- (b) essential requirements for the design, development and production of products with digital elements, and obligations for economic operators in relation to these products with respect to cybersecurity;
- (c) essential requirements for the vulnerability handling processes put in place by manufacturers to ensure the cybersecurity of products with digital elements during the ***time the product is expected to be in use***, and obligations for economic operators in relation to these processes;
- (d) rules on market surveillance, ***including monitoring***, and enforcement of the above-mentioned rules and requirements.

Article 2
Scope

1. This Regulation applies to products with digital elements ***made available on the market***, whose intended ***purpose*** or reasonably foreseeable use includes a direct or indirect logical or physical data connection to a device or network.
2. This Regulation does not apply to products with digital elements to which the following Union ***legal*** acts apply:
 - (a) Regulation (EU) 2017/745;

(b) Regulation (EU) 2017/746;

(c) Regulation (EU) 2019/2144.

3. This Regulation does not apply to products with digital elements that have been certified in accordance with Regulation (EU) 2018/1139.

3a. *This Regulation does not apply to equipment that falls within the scope of Directive 2014/90/EU of the European Parliament and of the Council³⁰.*

4. The application of this Regulation to products with digital elements covered by other Union rules laying down requirements that address all or some of the risks covered by the essential requirements set out in Annex I may be limited or excluded, where:

(a) such limitation or exclusion is consistent with the overall regulatory framework applying to those products; and

(b) the sectoral rules achieve the same ***or a higher*** level of protection as the one provided for by this Regulation.

The Commission is empowered to adopt delegated acts in accordance with Article 50 to ***supplement*** this Regulation ***by*** specifying whether such limitation or exclusion is necessary, the concerned products and rules, as well as the scope of the limitation, if relevant.

4a. *This Regulation does not apply to spare parts that are made available on the market to replace identical components in products with digital elements and that are manufactured according to the same specifications as the components they are intended to replace.*

5. This Regulation does not apply to products with digital elements developed ***or modified*** exclusively for national security ***or defence*** purposes or to products specifically designed to process classified information.

5a. *The obligations laid down in this Regulation shall not entail the supply of information the disclosure of which would be contrary to the essential interests of Member States' national security, public security or defence.*

³⁰ ***Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).***

Article 3
Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) ‘product with digital elements’ means any software or hardware product and its remote data processing solutions, including software or hardware components to be placed on the market separately;
- (2) ‘remote data processing’ means any data processing at a distance for which the software is designed and developed by the manufacturer or under the responsibility of the manufacturer, and the absence of which would prevent the product with digital elements from performing one of its functions;

█
(4a) ‘cybersecurity’ means cybersecurity as defined in Article 2, point (1), of Regulation (EU) 2019/881;

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- (6) ‘software’ means the part of an electronic information system which consists of computer code;
 - (7) ‘hardware’ means a physical electronic information system, or parts thereof capable of processing, storing or transmitting of digital data;
 - (8) ‘component’ means software or hardware intended for integration into an electronic information system;
 - (9) ‘electronic information system’ means any system, including electrical or electronic equipment, capable of processing, storing or transmitting digital data;
 - (10) ‘logical connection’ means a virtual representation of a data connection implemented through a software interface;

- (11) ‘physical connection’ means any connection between electronic information systems or components implemented using physical means, including through electrical, *optical* or mechanical interfaces, wires or radio waves;
- (12) ‘indirect connection’ means a connection to a device or network, which does not take place directly but rather as part of a larger system that is directly connectable to such device or network;
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- (15) ‘endpoint’ means any device that is connected to a network and serves as an entry point to that network;
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- (17) ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor, or any other natural or legal person who is subject to obligations *in relation to the manufacture of products or making them available on the market in accordance with* this Regulation;
- (18) ‘manufacturer’ means any natural or legal person who develops or manufactures products with digital elements or has products with digital elements designed, developed or manufactured, and markets them under his or her name or trademark, whether for payment, *monetisation* or free of charge;
- (18a)** *‘open-source software steward’ means any legal person, other than a manufacturer, which has the purpose or objective to systematically provide support on a sustained basis for the development of specific products with digital elements qualifying as free and open-source software that are intended for commercial activities, and ensures the viability of those products;*
- (19) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;

- (20) ‘importer’ means any natural or legal person established in the Union who places on the market a product with digital elements that bears the name or trademark of a natural or legal person established outside the Union;
- (21) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a product with digital elements available on the Union market without affecting its properties;
- (21a) ‘consumer’ means any natural person who acts for purposes which are outside that person’s trade, business, craft or profession;**
- (21b) ‘microenterprises’, ‘small enterprises’ and ‘medium-sized enterprises’ means microenterprises, small enterprises and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC³¹;**
- (21c) ‘support period’ means the period during which the manufacturer is required to ensure that vulnerabilities of the product with digital elements are handled effectively and in accordance with the essential requirements set out in Annex I, Section 2;**
- (22) ‘placing on the market’ means the first making available of a product with digital elements on the Union market;
- (23) ‘making available on the market’ means any supply of a product with digital elements for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (24) ‘intended purpose’ means the use for which a product with digital elements is intended by the manufacturer, including the specific context and conditions of use, as specified in the information supplied by the manufacturer in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;

³¹ ***Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (notified under document number C(2003)1422) (OJ L 124, 20.5.2003, p. 36).***

- (25) ‘reasonably foreseeable use’ means use that is not necessarily the intended purpose supplied by the manufacturer in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation, but which is likely to result from reasonably foreseeable human behaviour or technical operations or interactions;
- (26) ‘reasonably foreseeable misuse’ means the use of a product with digital elements in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;
- (27) ‘notifying authority’ means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;
- (28) ‘conformity assessment’ means the process of verifying whether the essential requirements set out in Annex I have been fulfilled;
- (29) ‘conformity assessment body’ means a **conformity assessment** body *as* defined in Article 2, **point (13)**, of Regulation (EU) No 765/2008;
- (30) ‘notified body’ means a conformity assessment body designated in accordance with Article 33 of this Regulation and other relevant Union harmonisation legislation;
- (31) ‘substantial modification’ means a change to the product with digital elements following its placing on the market, which affects the compliance of the product with digital elements with the essential requirements set out in Section 1 of Annex I or results in a modification to the intended **purpose** for which the product with digital elements has been assessed;
- (32) ‘CE marking’ means a marking by which a manufacturer indicates that a product with digital elements and the processes put in place by the manufacturer are in conformity with the essential requirements set out in Annex I and other applicable Union harmonisation legislation providing for its affixing;
- (32a) ***‘Union harmonisation legislation’ means Union legislation listed in Annex I to Regulation (EU) 2019/1020 and any other Union legislation harmonising the conditions for the marketing of products to which that Regulation applies;***

- (33) ‘market surveillance authority’ means **a market surveillance** authority as defined in Article 3, point (4), of Regulation (EU) 2019/1020;
- (34) ‘harmonised standard’ means a harmonised standard as defined in Article 2, point (1)(c), of Regulation (EU) No 1025/2012;
- (34a) **‘international standard’ means an international standard as defined in Article 2, point (1)(a) of Regulation (EU) No 1025/2012;**
- (34b) **‘European standard’ means a European standard as defined in Article 2, point (1)(b) of Regulation (EU) No 1025/2012;**
- (35) ‘cybersecurity risk’ means **the potential for loss or disruption caused by an incident and is to be expressed as a combination of the magnitude of such loss or disruption and the likelihood of occurrence of the incident;**
- (36) ‘significant cybersecurity risk’ means a cybersecurity risk which, based on its technical characteristics, can be assumed to have a high likelihood of an incident that could lead to a severe negative impact, including by causing considerable material or non-material loss or disruption;
- (37) ‘software bill of materials’ **or ‘SBOM’** means a formal record containing details and supply chain relationships of components included in the software elements of a product with digital elements;
- (38) ‘vulnerability’ means a **weakness, susceptibility or flaw of a product with digital elements that can be exploited by a cyber threat;**
- (38a) **‘exploitable vulnerability’ means a vulnerability that has the potential to be effectively used by an adversary under practical operational conditions;**
- (39) ‘actively exploited vulnerability’ means a vulnerability for which there is reliable evidence that **a malicious** ■ actor **has exploited it in** a system without permission of the system owner;
- (39a) **‘incident’ means an incident as defined in Article 6, point (6) of Directive (EU) 2022/2555;**

- (39b) *‘incident having an impact on the security of the product with digital elements’ means an incident which negatively affects or is capable of negatively affecting the ability of a manufacturer’s product with digital elements to protect the availability, authenticity, integrity or confidentiality of data or functions.*
- (39c) *‘near miss’ means a near miss as defined in Article 6, point (5), of Directive (EU) 2022/2555;*
- (39d) *‘cyber threat’ means a cyber threat as defined in Article 2, point (8), of Regulation (EU) 2019/881;*
- (40) *‘personal data’ means **personal** data as defined in Article 4, point (1), of Regulation (EU) 2016/679.*
- (40a) *‘free and open-source software’ means software the source code of which is openly shared and which is made available under a free and open-source license which provides for all rights to make it freely accessible, usable, modifiable and redistributable;*
- (41) *‘recall’ means recall as defined in Article 3, point (22), of Regulation (EU) 2019/1020;*
- (42) *‘withdrawal’ means withdrawal as defined in Article 3, point (23), of Regulation (EU) 2019/1020.*
- (40g) *‘CSIRT designated as coordinator’ means a CSIRT designated as coordinator pursuant to Article 12(1) of Directive (EU) 2022/2555.*

Article 4
Free movement

1. Member States shall not impede, for the matters covered by this Regulation, the making available on the market of products with digital elements which comply with this Regulation.
2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the presentation and use of a product with digital elements which does not comply with this Regulation, ***including its prototypes, provided that a visible sign clearly indicates that it does not comply with this Regulation and will not be made available on the market until it has been brought into conformity.***
3. Member States shall not prevent the making available of unfinished software which does not comply with this Regulation provided that the software is only made available for a limited period required for testing purposes and that a visible sign clearly indicates that it does not comply with this Regulation and will not be available on the market for purposes other than testing.
4. ***Paragraph 3 does not apply to safety components as defined under other Union harmonisation legislation.***

Article 4a

Procurement or use of products with digital elements

1. *This Regulation shall not prevent Member States from subjecting products with digital elements to additional cybersecurity requirements for the procurement or use of those products for specific purposes, including when these products will be procured or used for defence or national security purposes, provided that such requirements are consistent with Member States' obligations laid down in Union law and that they are necessary and proportionate for the achievement of those purposes.*
2. *Without prejudice to Directive (EU) 2014/24 and Directive (EU) 2014/25, when procuring products with digital elements that fall within the scope of this Regulation, Member States shall ensure that the compliance with the essential requirements set out in Annex I to this Regulation, including the manufacturers' ability to effectively handle vulnerabilities, are taken into consideration in the procurement procedures.*

Article 5

Requirements for products with digital elements

Products with digital elements shall only be made available on the market where:

- (1) they meet the essential requirements set out in Section 1 of Annex I, under the condition that they are properly installed, maintained, used for their intended purpose or under conditions which can reasonably be foreseen, and, where applicable, *having installed the necessary security updates*, and
- (2) the processes put in place by the manufacturer comply with the essential requirements set out in Section 2 of Annex I.

Article 6

Important products with digital elements

1. Products with digital elements *which have the core functionality of* a category *that* is listed in Annex III *to this Regulation* shall be considered *important* products with digital elements *and subject to the conformity assessment procedures referred to in Article 24 (2) and (3). The integration of a product with digital elements which has the core functionality listed in Annex III does not in itself render the product in which it is integrated subject to the conformity assessment procedures referred to in Article 24 (2) and (3).*
- 1a. *The categories of products with digital elements referred to in paragraph 1 are divided into class I and class II as set out in Annex III and meet one or both of the following criteria:*
 - (a) *the product with digital elements performs primarily functions critical to the cybersecurity of other products, networks or services, including securing authentication and access, intrusion prevention and detection, endpoint security or network protection;*
 - (b) *the product with digital elements performs a function which carries a significant risk of adverse effects in terms of its intensity and ability to disrupt, control or cause damage to a large number of other products or to the health, security or safety of its users through direct manipulation, such as a central system function, including network management, configuration control, virtualisation or processing of personal data.*

2. The Commission is empowered to adopt delegated acts in accordance with Article 50 to amend Annex III by including in the list *within each class of the* categories of [] products with digital elements a new category *and specifying its definition, moving a category of products from one class to the other* or withdrawing an existing one from that list. When assessing the need to amend the list in Annex III, the Commission shall take into account the *cybersecurity-related functionalities or the function and the level of cybersecurity risk posed by the products with digital elements as set out by the criteria referred to in paragraph 1a.*

The delegated acts referred to in the first subparagraph shall provide, where appropriate, in particular where a new category of important products with digital elements is added to class I or II or moved from class I to II as set out in Annex III, for a minimum transition period of 12 months, unless a shorter transition period is justified for imperative reasons of urgency, before the relevant conformity assessment procedures referred to in Article 24 (2) and (3) start applying.

- []
3. *By ... [12 months from the date of entry into force of this Regulation], the Commission shall adopt an implementing act specifying the technical description of the [] categories of products with digital elements under class I and class II as set out in Annex III and the technical description of the categories of products with digital elements set out in Annex IIIa.*

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 51(2).

[]

Article 6a

Critical products with digital elements

- 1. The Commission is empowered to adopt delegated acts in accordance with Article 50 to supplement this Regulation to determine which products with digital elements that have the core functionality of a category that is listed in Annex IIIa to this Regulation shall be required to obtain a European cybersecurity certificate at assurance level at least substantial under a European cybersecurity certification scheme adopted pursuant to Regulation (EU) 2019/881 to demonstrate conformity with the essential requirements set out in Annex I to this Regulation or parts thereof, provided that a European cybersecurity certification scheme covering those categories of products with digital elements has been adopted pursuant to Regulation (EU) 2019/881, and is available to manufacturers. The delegated acts shall specify the required assurance level that shall be proportionate to the level of cybersecurity risk associated with the products with digital elements and shall take account of their intended purpose, including their critical dependency by essential entities of a type referred to in Article 3 to Directive (EU) 2022/2555.*

Before adopting such delegated acts, the Commission shall carry out an assessment of the potential market impact of the envisaged measures and shall carry out consultations with relevant stakeholders, including the European Cybersecurity Certification Group referred to in Regulation (EU) 2019/881. The assessment shall take into account the readiness and the capacity level of the Member States for the implementation of the respective European cybersecurity certification scheme. Where no delegated act as referred to in the first subparagraph has been adopted, products with digital elements which have the core functionality of a category listed in Annex IIIa shall be subject to the conformity assessment procedures referred to in Article 24(3).

The delegated acts referred to in the first subparagraph shall provide for a minimum transition period of 6 months, unless a shorter transition period is justified for imperative reasons of urgency, for their application.

2. The Commission is empowered to adopt delegated acts in accordance with Article 50 to **amend Annex IIIa by adding or withdrawing** categories of critical products with digital elements. **When determining such categories of critical products with digital elements and the required assurance level, in accordance with paragraph 1**, the Commission shall take into account the **criteria referred to in Article 6(1a) and ensure that** the category of products with digital elements **meet at least one** of the **following criteria**:

- (a) **the extent to which there is a critical dependency of essential entities** referred to in **Article 3 of Directive (EU) 2022/2555 on the category of products with digital elements**;
- (b) **the extent to which incidents and exploited vulnerabilities concerning the category** of products with digital elements **can lead to serious disruptions to critical supply chains across the internal market**.

Before adopting such delegated acts, the Commission shall carry out an assessment of the type referred to in paragraph 1 second subparagraph.

The delegated acts referred to in the first subparagraph shall provide for a minimum transition period of 6 months, unless a shorter transition period is justified for imperative reasons of urgency.

Article 6b

Stakeholder consultation

1. **When preparing measures for the implementation of this Regulation, the Commission shall consult and take into account the views of relevant stakeholders, such as relevant Member States' authorities, private sector, including micro, small and medium-sized enterprises, open-source software community, consumer associations, academia, and relevant Union agencies or bodies or expert groups established at Union level. In particular, the Commission shall in a structured manner, and where appropriate, consult and seek the views of these stakeholders when:**

- (a) **Preparing the guidelines referred to in Article 17c;**

- (b) Preparing the specific technical descriptions of the product categories as set out in Annex III as per Article 6(3), when assessing the need for potential updates to the list of product categories as per Article 6(2) and Article 6a(2), or when carrying out the assessment of the potential market impact referred to in Article 6a(1), without prejudice to the provisions of Article 50 of this Regulation;*
 - (c) Undertaking preparatory work for the evaluation and review of this Regulation.*
- 2. The Commission shall organise regular consultation and information sessions, at least once a year, to gather the views of the stakeholders referred to in paragraph 1 on the implementation of this Regulation.*

Article 6c

Enhancing skills in a cyber resilient digital environment

For the purposes of this Regulation and in order to respond to the needs of professionals in support of the implementation of this Regulation, Member States, where appropriate with the support of the Commission, European Cybersecurity Competence Center and ENISA, while fully respecting the responsibility of the Member States in the education field, shall promote measures and strategies aiming at:

- a) developing cyber security skills and creating organisational and technological tools to ensure sufficient availability of skilled professionals in order to support the activities of the market surveillance authorities and conformity assessment bodies;*
- (b) increasing the collaboration between the private sector, economic operators, including via re-skilling or up-skilling for manufacturers' employees, consumers, training providers as well public administration, expanding the options for young people to access jobs in this sector.*

Article 7
General product safety

By way of derogation from Article 2(1), third subparagraph, point (b), of Regulation (EU) 2023/988, Chapter III, Section 1, Chapters V and VII, and Chapters IX to XI of *that* Regulation shall apply to products with *digital elements with* respect to *aspects and risks or categories of risks* not covered by this Regulation *where those products are not subject to specific safety requirements imposed by other Union harmonisation legislation as defined in Article 3, point (27) of Regulation (EU) 2023/988.*

Article 8
High-risk AI systems³²

1. *Without prejudice to the requirements relating to accuracy and robustness set out in Article [Article 15] of Regulation [the AI Regulation], products with digital elements which fall within the scope of this Regulation and which are classified as high-risk AI systems pursuant to Article [Article 6] of Regulation [the AI Regulation] shall be deemed compliant with the cybersecurity requirements set out in Article [Article 15] of that Regulation if:*
 - (a) they fulfil the essential requirements set out in Section 1 of Annex I to this Regulation;*
 - (b) the processes put in place by the manufacturer are compliant with the essential requirements set out in Section 2 of Annex I to this Regulation; and*
 - (c) the achievement of the level of cybersecurity protection required under Article [Article 15] of Regulation [the AI Regulation] is demonstrated in the EU declaration of conformity issued under this Regulation.*

³² *Technical note: the co-legislators have decided that this provision should be deleted if the planning for adoption and publication of the Artificial Intelligence Act (2021/0106(COD)) is significantly longer than the one of the Cyber Resilience Act (2022/0272(COD)), and will be introduced as an amendment through the Artificial Intelligence Act.*

2. For the products ***with digital elements*** and cybersecurity requirements referred to in paragraph 1, the relevant conformity assessment procedure as required by Article [Article 43] of Regulation [AI Regulation] shall apply. For the purpose of that assessment, notified bodies which are ***competent*** to control the conformity of the high-risk AI systems under [Regulation [AI Regulation] shall be also ***competent*** to control the conformity of [high-risk AI systems ***which fall*** within the scope of this Regulation with the requirements set out in Annex I to this Regulation, provided that the compliance of those notified bodies with the requirements laid down in Article 29 of this Regulation ***has*** been assessed in the context of the notification procedure under Regulation [AI Regulation].
3. By ***way of*** derogation from paragraph 2, ***important*** products with digital elements listed in Annex III ***to*** this Regulation, which ***are subject to*** the conformity assessment procedures referred to in Articles 24(2)(a), 24(2)(b), ***24(3) of this Regulation and critical products with digital elements listed in Annex IIIa which are required to obtain a European cybersecurity certificate according to Article 6a (1) of this Regulation or, absent that, which are subject to the conformity assessment procedures referred to in Article 24(3) of this Regulation,*** and which are also classified as high-risk AI systems ***pursuant*** to Article [Article 6] of [Regulation [AI Regulation], and to which the conformity assessment procedure based on internal control referred to in Annex [Annex VI] to Regulation [the AI Regulation] applies, shall be subject to the conformity assessment procedures [required ***under*** this Regulation in so far as the essential requirements of this Regulation are concerned.
- 3a. ***Manufacturers of products with digital elements referred to in paragraph 1 of this Article may participate in the AI regulatory sandboxes referred to in Article 53 of Regulation [the AI Regulation].***

█

CHAPTER II
OBLIGATIONS OF ECONOMIC OPERATORS *AND PROVISIONS IN RELATION TO FREE
AND OPEN-SOURCE SOFTWARE*

Article 10

Obligations of manufacturers

1. When placing a product with digital elements on the market, manufacturers shall ensure that it has been designed, developed and produced in accordance with the essential requirements set out in Section 1 of Annex I.
2. For the purposes of complying with the obligation laid down in paragraph 1, manufacturers shall undertake an assessment of the cybersecurity risks associated with a product with digital elements and take the outcome of that assessment into account during the planning, design, development, production, delivery and maintenance phases of the product with digital elements with a view to minimising cybersecurity risks, preventing security incidents and minimising the impacts of such incidents, including in relation to the health and safety of users.
 - 2a. *The cybersecurity risk assessment shall be documented and updated as appropriate during the support period. It shall comprise at least an analysis of cybersecurity risks based on the intended purpose and reasonably foreseeable use, as well as the conditions of use of the product with digital elements, such as the operational environment or the assets to be protected, taking into account the time the product is expected to be in use. The cybersecurity risk assessment shall indicate whether and, if so, in what manner the security requirements set out in point 3 of Section 1 of Annex I are applicable to the respective product with digital elements and how these are implemented as informed by the cybersecurity risk assessment. It shall also indicate how the manufacturer will apply point 1 of Section 1 of the Annex I and the vulnerability handling requirements in Section 2 of Annex I.*

3. When placing a product with digital elements on the market, the manufacturer shall include a cybersecurity risk assessment in the technical documentation as set out in Article 23 and Annex V. For products with digital elements referred to in Articles 8 and 24(4) that are also subject to other Union acts, the cybersecurity risk assessment may be part of the risk assessment required by those respective Union acts. Where certain essential requirements are not applicable to the marketed product with digital elements, the manufacturer shall include a clear justification in that documentation.
4. For the purposes of complying with the obligation laid down in paragraph 1, manufacturers shall exercise due diligence when integrating components sourced from third parties in *a manner* that such components do not compromise the *cybersecurity of the product* with digital elements, *including when integrating components of free and open-source software that have not been made available on the market in the course of a commercial activity*.
 - 4a *Manufacturers shall, upon identifying a vulnerability in a component, including in an open source-component, which is integrated in the product with digital elements, report the vulnerability to the person or entity manufacturing or maintaining the component, and address and remediate the vulnerability in accordance with the vulnerability handling requirements set out in Annex I, Section 2.*

Where manufacturers have developed a software or hardware modification to address the vulnerability in that component, they shall share the relevant code or documentation with the person or entity manufacturing or maintaining the component, where appropriate in a machine-readable format.
5. The manufacturer shall systematically document, in a manner that is proportionate to the nature and the cybersecurity risks, relevant cybersecurity aspects concerning the product with digital elements, including vulnerabilities *it becomes* aware of and any relevant information provided by third parties, and, where applicable, update the *cybersecurity* risk assessment of the product.

6. ***Manufacturers shall ensure***, when placing a product with digital elements on the market, and ***thereafter*** for the ***support period***, ***that vulnerabilities of that product, including its components, are handled effectively and in accordance with the essential requirements set out in Section 2 of Annex I.***

Manufacturers shall determine the support period referred to in the first subparagraph of this paragraph that reflects the time the product is expected to be in use, taking into account in particular reasonable users' expectations, the nature of the product, including its intended purpose, as well as relevant Union law determining the lifetime of products with digital elements. When determining the support period, manufacturers may also take into account the support period of products with digital elements offering a similar functionality placed on the market by other manufacturers, the availability of the operating environment, the support period of integrated components that provide core functions and are sourced from third parties as well as relevant guidance provided by the dedicated administrative cooperation group (ADCO) established under Article 41(11) or the Commission. The above-mentioned elements to determine the support period shall be considered in a manner that ensures proportionality.

Without prejudice to the second subparagraph of this paragraph, the support period shall be at least five years. When the product with digital elements is expected to be in use for less than five years, the support period shall correspond to the expected use time.

Taking into account the ADCO recommendations referred to in Article 41(11a), the Commission may, by means of delegated acts, specify the minimum support period for specific product categories where the market surveillance data suggests inadequate support periods.

Manufacturers shall include information that was taken into account to determine the support period of a product with digital elements in the technical documentation as set out in Annex V.

Manufacturers shall have appropriate policies and procedures, including coordinated vulnerability disclosure policies, referred to in Section 2, point (5), of Annex I, to process and remediate potential vulnerabilities in the product with digital elements reported from internal or external sources.

- 6a. *Manufacturers shall ensure that each security update, referred to in Section 2, point (8), of Annex I, which has been made available to users during the support period shall remain available after it has been issued for a minimum duration of 10 years or for the remainder of the support period, whichever is longer.*
- 6b. *Where a manufacturer has placed subsequent substantially modified versions of a software product on the market, compliance with the essential requirement laid down in point 2 of section 2 of Annex I may be ensured only for the version that it has last placed on the market. The manufacturer may do so only if the users of the versions that have been previously placed on the market have access to the version last placed on the market free of charge and do not incur additional costs to adjust the hardware and software environment in which they use the original version of that product.*
- 6c. *Manufacturers may maintain public software archives enhancing user access to historical versions. In those cases, users must be clearly informed in an easily accessible manner about risks associated with using unsupported software.*
7. Before placing a product with digital elements on the market, manufacturers shall draw up the technical documentation referred to in Article 23.

They shall carry out the chosen conformity assessment procedures referred to in Article 24 or have them carried out.

Where compliance of the product with digital elements with the essential requirements set out in Section 1 of Annex I and of the processes put in place by the manufacturer with the essential requirements set out in Section 2 of Annex I has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity in accordance with Article 20 and affix the CE marking in accordance with Article 22.

8. Manufacturers shall keep the technical documentation and the EU declaration of conformity **■** at the disposal of the market surveillance authorities for *at least ten years or the support period, whichever is longer*, after the product with digital elements has been placed on the market.

9. Manufacturers shall ensure that procedures are in place for products with digital elements that are part of a series of production to remain in conformity ***with the requirements of this Regulation***. The manufacturer shall adequately take into account changes in the development and production process or in the design or characteristics of the product with digital elements and changes in the harmonised standards, European cybersecurity certification schemes or the common specifications referred to in Article 18 by reference to which the conformity of the product with digital elements is declared or by application of which its conformity is verified.

9a. Manufacturers shall ensure that their products with digital elements bear a type, batch or serial number or other element allowing their identification, or, where that is not possible, ensure that this information is provided on their packaging or in a document accompanying the product with digital elements.

9b. Manufacturers shall indicate the name, registered trade name or registered trade mark of the manufacturer, and the postal address, email address or other digital contact as well as, where applicable, the website at which the manufacturer can be contacted, on the product with digital elements, on its packaging or in a document accompanying the product with digital elements. This information shall also be included in the information and instructions to the user referred to in Annex II. The contact details shall be in a language which can be easily understood by users and market surveillance authorities.

9c. For the purposes of this Regulation, manufacturers shall designate a single point of contact to enable users to communicate directly and rapidly with them, including in order to facilitate reporting on cybersecurity vulnerabilities of the product with digital elements.

Manufacturers shall ensure that the single point of contact can be easy to identify by the users. They shall also include the single point of contact in the information and instructions to the user set out in Annex II.

The single point of contact shall allow users to choose the means of communication, which shall not rely exclusively on automated tools.

10. Manufacturers shall ensure that products with digital elements are accompanied by the information and instructions set out in Annex II, in an electronic or physical form. Such information and instructions shall be **provided** in a language which can be easily understood by users **and market surveillance authorities**. They shall be clear, understandable, intelligible and legible. They shall allow for a secure installation, operation and use of the products with digital elements. **Manufacturers shall keep the information and instructions set out in Annex II at the disposal of users and market surveillance authorities for at least ten years or for the support period, whichever is longer. Where such information and instructions are provided online, manufacturers shall ensure that they are accessible and user-friendly and available online for at least ten years or the support period of the product with digital elements, whichever is longer.**
- 10a. Manufacturers shall ensure that the end of the support period as referred to in paragraph 6, including at least the month and year, is clearly and understandably specified at the time of purchase, in an easily accessible manner and where applicable on the product with digital elements, its packaging or by digital means.**
- Where technically feasible in light of the nature of the product with digital elements, manufacturers shall display a notification to users informing them that their product with digital elements has reached the end of its support period.**
11. Manufacturers shall either provide **a copy of** the EU declaration of conformity **or a simplified EU declaration of conformity** with the product with digital elements. **Where a simplified EU declaration of conformity is provided, it shall contain** the **exact** internet address at which the **full** EU declaration of conformity can be accessed.
12. From the placing on the market and for **at least the support period** **■**, manufacturers who know or have reason to believe that the product with digital elements or the processes put in place by the manufacturer are not in conformity with the essential requirements set out in Annex I shall immediately take the corrective measures necessary to bring that product with digital elements or the manufacturer's processes into conformity, to withdraw or to recall the product, as appropriate.

13. Manufacturers shall, further to a reasoned request from a market surveillance authority, provide that authority, in a language which can be easily understood by it, with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the product with digital elements and of the processes put in place by the manufacturer with the essential requirements set out in Annex I. They shall cooperate with that authority, at its request, on any measures taken to eliminate the cybersecurity risks posed by the product with digital elements, which they have placed on the market.
14. A manufacturer that ceases its operations and, as a result, is not able to comply with the obligations laid down in this Regulation shall inform, before the cease of operation takes effect, the relevant market surveillance authorities about this situation, as well as, by any means available and to the extent possible, the users of the concerned products with digital elements placed on the market.
15. The Commission may, by means of *implementing acts, taking into account European or international standards and best practices*, specify the format and elements of the software bill of materials set out in Section 2, point (1), of Annex I. Those *implementing acts* shall be adopted in accordance with the examination procedure referred to in Article 51(2).
16. *In order to assess the dependency of Member States as well as the Union as a whole on software components and in particular on components qualifying as free and open-source software, the ADCO may decide to conduct a Union wide dependency assessment for specific categories of products with digital elements. For that purpose, market surveillance authorities may request manufacturers of such categories of products with digital elements to provide the relevant software bills of materials as referred to in point 1 of section 2 of Annex I. Based on such information, the market surveillance authorities may provide the ADCO with anonymised and aggregated information about software dependencies. The ADCO shall submit a report on the results of the dependency assessment to the Cooperation Group established under Article 14 of Directive (EU) 2022/2555.*

Article 11

Reporting obligations of manufacturers

1. *A manufacturer shall ■ notify ■ any actively exploited vulnerability contained in the product with digital elements **that it becomes aware of simultaneously** to the CSIRT designated **as coordinator**, in accordance with **paragraph 7 of this Article, and to ENISA. The manufacturer shall notify that actively exploited vulnerability via the single reporting platform established in Article 11b.***

2. *For the purpose of the notification referred to in paragraph 1, the manufacturers shall submit:*
 - (a) *an early warning notification on an actively exploited vulnerability without undue delay and in any event within 24 hours of the manufacturer becoming aware of its existence, indicating, where applicable, the Member States on the territory of which the manufacturer is aware that their product with digital elements has been made available;*(b) *unless the relevant information has already been provided, a vulnerability notification, without undue delay and in any event within 72 hours of the manufacturer becoming aware of the actively exploited vulnerability, which shall provide general information, as available, about the product with digital elements concerned, the general nature of the exploit and of the respective vulnerability as well as any corrective or mitigating measures taken, and corrective or mitigating measures that users can take. The notification shall also indicate, where applicable, how sensitive the manufacturer deems the notified information to be;*

 - (c) *unless the relevant information has already been provided, a final report, no later than 14 days after a corrective or mitigating measure is available, including at least the following:*
 - (i) *a description of the vulnerability, including its severity and impact;*

 - (ii) *where available, information concerning any malicious actor that has exploited or that is exploiting the vulnerability;*

(iii) details about the security update or other corrective measures that have been made available to remedy the vulnerability.

3. *A manufacturer shall ■ notify ■ any severe incident having an impact on the security of the product with digital elements that it becomes aware of simultaneously to the CSIRT designated as coordinator, in accordance with paragraph 7 of this Article, and to ENISA. The manufacturer shall notify that incident via the single reporting platform established in Article 11b.*
4. *For the purpose of the notification referred to in paragraph 3, the manufacturers shall submit:*
- (a) an early warning notification on a severe incident having an impact on the security of the product with digital elements without undue delay and in any event within 24 hours of the manufacturer becoming aware of it, including at least whether the incident is suspected of being caused by unlawful or malicious acts. The notification shall also indicate, where applicable, the Member States on the territory of which the manufacturer is aware that their product with digital elements has been made available;*
 - (b) unless the relevant information has already been provided, an incident notification, without undue delay and in any event within 72 hours of the manufacturer becoming aware of the incident, which shall provide general information, as available, about the nature of the incident, an initial assessment of the incident, as well as any corrective or mitigating measures taken, and corrective or mitigating measures that users can take. The notification shall also indicate, where applicable, how sensitive the manufacturer deems the notified information to be;*
 - (c) unless the relevant information has already been provided, a final report, within one month after the submission of the incident notification under point (b), including at least the following:*
 - (i) a detailed description of the incident, including its severity and impact;*

- (ii) *the type of threat or root cause that is likely to have triggered the incident;*
- (iii) *applied and ongoing mitigation measures.*

5. *For the purpose of paragraph 3, an incident having an impact on the security of the product with digital elements shall be considered to be severe, where:*
- (a) *it negatively affects or is capable to negatively affect the ability of a manufacturer's product with digital elements to protect the availability, authenticity, integrity or confidentiality of sensitive or important data or functions;*
or
 - (b) *it has led or is capable to lead to the introduction or execution of malicious code in a product with digital elements or in the network and information systems of a user of the product with digital elements.*
6. *Where necessary, the CSIRT designated as coordinator initially receiving the notification may request manufacturers to provide an intermediate report on relevant status updates about the actively exploited vulnerability or severe incident having an impact on the security of the product with digital elements.*
7. *The notifications referred to in paragraphs 1 and 3 shall be submitted via the single reporting platform referred to in Article 11b using one of the electronic notification end-points referred to in Article 11b(1). The notification shall be submitted using the electronic notification end-point of the CSIRT designated as coordinator of the Member State where the manufacturers have their main establishment in the Union and shall be simultaneously accessible to ENISA.*

For the purposes of this Regulation, a manufacturer shall be considered to have its main establishment in the Union in the Member State where the decisions related to the cybersecurity of its products with digital elements are predominantly taken. If such a Member State cannot be determined, the main establishment shall be considered to be in the Member State where the manufacturer concerned has the establishment with the highest number of employees in the Union.

Where a manufacturer has no main establishment in the Union, it shall submit the notifications referred to in paragraphs 1 and 3 using the electronic notification end-point of the CSIRT designated as coordinator in the Member State determined pursuant to the following order and based on the information available to the manufacturer:

- (a) the Member State in which the authorised representative acting on behalf of the manufacturer for the highest number of the products with digital elements is established;*
- (b) the Member State in which the importer placing on the market the highest number of products with digital elements of that manufacturer is established;*
- (c) the Member State in which the distributor making available the highest number of products with digital elements of that manufacturer is established;*
- (d) the Member State in which the highest number of users of the products with digital elements of that manufacturer are located.*

In relation to point (d) of the third subparagraph, a manufacturer may submit notifications related to any subsequent actively exploited vulnerability or severe incident having an impact on the security of the product with digital elements to the same CSIRT designated as coordinator to which it first reported.

■

8. The manufacturer shall inform, ■ after becoming aware, the *impacted* users of the product with digital elements, *and where appropriate all users*, about *an actively exploited vulnerability or a severe incident having an impact on the security of the product with digital elements* and, where necessary, about *risk mitigation and any* corrective measures that the *users* can deploy to mitigate the impact of *that vulnerability or incident, where appropriate in a structured and easily automatically processible machine-readable format. Where the manufacturer fails to inform the users of the product with digital elements in a timely manner, the notified CSIRTs may provide such information to the users when considered proportionate and necessary for preventing or mitigating the impact of that vulnerability or incident.*

9. The Commission may, by means of implementing acts, specify further the format and *procedures* of the notifications *referred to in this Article as well as in Articles 11a and 11b*. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2). *The Commission shall cooperate with the CSIRTs network and ENISA in preparing these draft implementing acts.*

The Commission shall adopt delegated acts in accordance with Article 50 to supplement this Regulation by specifying the terms and conditions for applying the cybersecurity related grounds in relation to delaying the dissemination of notifications as referred to in paragraph 2 of Article 11b. Those delegated acts shall be adopted by ... [12 months from the date of entry into force of this Regulation]. The Commission shall cooperate with the CSIRTs network and ENISA in preparing the draft delegated acts.



Article 11a

Voluntary reporting

1. *The manufacturers as well as other natural or legal persons may notify any vulnerability contained in the product with digital elements as well as cyber threats that could affect the risk profile of the product with digital elements on a voluntary basis to a CSIRT designated as coordinator or ENISA.*
2. *The manufacturers as well as other natural or legal persons may notify any incident having an impact on the security of the product with digital elements as well as near misses that could have resulted in an incident having an impact on the security of the product with digital elements on a voluntary basis to a CSIRT designated as coordinator or ENISA.*
3. *The CSIRT designated as coordinator or ENISA shall process the notifications referred to in paragraphs 1 and 2 of this Article in accordance with the procedure laid down in Article 11b.*

The CSIRT designated as coordinator may prioritise the processing of mandatory notifications over voluntary notifications.

4. *Where a natural or legal person other than the manufacturer notifies an actively exploited vulnerability or a severe incident having an impact on the security of a product with digital elements in accordance with paragraphs 1 or 2 of this Article, the CSIRT designated as coordinator shall without undue delay inform the manufacturer.*
5. *The CSIRTs designated as coordinator as well as ENISA shall ensure the confidentiality and appropriate protection of the information provided by the notifying natural or legal person. Without prejudice to the prevention, investigation, detection and prosecution of criminal offences, voluntary reporting shall not result in the imposition of any additional obligations upon the notifying natural or legal person to which it would not have been subject had it not submitted the notification.*

Article 11b

Establishment of a single reporting platform

- 1. For the purposes of the notifications referred to in paragraphs 1 and 3 of Article 11 and paragraphs 1 and 2 of Article 11a and in order to simplify the reporting obligations of manufacturers, a single reporting platform shall be established, and the day-to-day operations managed and maintained by ENISA. The architecture of the single reporting platform shall allow Member States and ENISA to put in place their own electronic notification end-points.*

- 2. After receiving a notification, the CSIRT designated as coordinator initially receiving the notification shall, without delay, disseminate the notification via the single reporting platform to all the CSIRTs designated as coordinators on whose territory the manufacturer has indicated that the product with digital elements has been made available. In exceptional circumstances and in particular upon request by the manufacturer and in light of the level of sensitivity of the notified information as indicated by the manufacturer under paragraph 2(a) of Article 11, the dissemination of the notification may be delayed based on justified cybersecurity related grounds for a period of time that is strictly necessary, including in cases where a vulnerability is subject to a coordinated vulnerability disclosure procedure as referred to in Article 12(1) of Directive (EU) 2022/2555. Where a CSIRT decides to withhold a notification, it shall immediately inform ENISA about the decision and provide both a justification for withholding the notification as well as an indication of when it will disseminate the notification in accordance with the dissemination procedure laid down in this paragraph. ENISA may support the CSIRT on the application of cybersecurity related grounds in relation to delaying the dissemination of the notification.*

In particularly exceptional circumstances, when the manufacturer marks in a notification referred to in point (b) of Article 11 (2) that:

- (i) the notified vulnerability has been actively exploited by a malicious actor and that, according to the information available, it has been exploited in no other Member State than the one of the CSIRT to which the manufacturer has notified the vulnerability, or*
- (ii) any immediate further dissemination of the notified vulnerability would likely result in the supply of information the disclosure of which would be contrary to the essential interests of that Member State, or*
- (iii) the notified vulnerability poses an imminent high cybersecurity risk stemming from the further dissemination,*

only the information that a notification was made by the manufacturer, the general information about the product, general nature of the exploit and the information that security related grounds were raised are simultaneously made available to ENISA until the full notification is disseminated to the CSIRTs concerned and ENISA. Where, based on this information, ENISA considers that there is a systemic risk affecting security in the internal market, it shall recommend to the recipient CSIRT to disseminate the full notification to the other CSIRTs and ENISA.

- 3. After receiving a notification regarding an actively exploited vulnerability in a product with digital elements or regarding a severe incident having an impact on the security of a product with digital elements, the CSIRTs shall provide the market surveillance authorities of their respective Member States with the notified information necessary for the market surveillance authorities to fulfil their obligations under this Regulation.*
- 4. ENISA shall take appropriate and proportionate technical, operational and organisational measures to manage the risks posed to the security of the single reporting platform and the information submitted or disseminated via the platform. It shall notify without undue delay any security incident affecting the single reporting platform to the CSIRTs network, established pursuant to Article 15 of Directive (EU) 2022/2555, as well as to the Commission.*

5. *ENISA, in cooperation with the CSIRTs network, shall provide and implement specifications on the technical, operational and organisational measures regarding the establishment, maintenance and secure operation of the single reporting platform referred to in paragraph 1 of this Article, including at least the security arrangements related to the establishment, operation and maintenance of the platform, as well as the electronic notification end-points set up by the CSIRTs at national level and ENISA at Union level, including procedural aspects to ensure that, where a notified vulnerability has no corrective or mitigating measures available, information about said vulnerability is shared in line with strict security protocols and on a need-to-know-basis.*
6. *Where a CSIRT designated as coordinator has been made aware of an actively exploited vulnerability as part of a coordinated vulnerability disclosure procedure as referred to in Article 12(1) of Directive (EU) 2022/2555, the CSIRT designated as coordinator initially receiving the notification may delay the dissemination of the respective notification via the single reporting platform based on justified cybersecurity related grounds for a period of time that is strictly necessary and until consent for disclosure by the involved coordinated vulnerability disclosure-parties is reached. This does not prevent manufacturers from notifying such a vulnerability on a voluntary basis in accordance with the procedure laid down in this Article.*

Article 11c

Other provisions related to reporting

1. *ENISA may submit to the European cyber crisis liaison organisation network (EU-CyCLONe) established under Article 16 of Directive (EU) 2022/2555 information notified pursuant to paragraphs 1 and 3 of Article 11 and paragraphs 1 and 2 of Article 11a if such information is relevant for the coordinated management of large-scale cybersecurity incidents and crises at an operational level. For the purpose of determining such relevance, ENISA may consider technical analyses performed by the CSIRTs network, where available.*

2. *Where public awareness is necessary to prevent or mitigate a severe incident having an impact on the security of the product with digital elements or to deal with an ongoing incident, or where disclosure of the incident is otherwise in the public interest, the CSIRT designated as coordinator of the relevant Member State, may, after consulting the manufacturer concerned, and where appropriate in cooperation with ENISA, inform the public about the incident or require the manufacturer to do so.*
3. *ENISA, on the basis of the notifications received pursuant to paragraphs 1 and 3 of Article 11 and paragraphs 1 or 2 of Article 11a, shall prepare a biennial technical report on emerging trends regarding cybersecurity risks in products with digital elements and submit it to the Cooperation Group established under Article 14 of Directive (EU) 2022/2555. The first such report shall be submitted within 24 months after the obligations laid down in paragraphs 1 and 3 of Article 11 start applying. ENISA shall include relevant information from its technical reports in its report on the state of cybersecurity in the Union pursuant to Article 18 of Directive (EU) 2022/2555.*
4. *The mere act of notification in accordance with paragraphs 1 or 3 of Article 11 or paragraphs 1 or 2 of Article 11a shall not subject the notifying natural or legal person to increased liability.*
5. *After a security update or another form of corrective or mitigating measure is available, ENISA shall, in agreement with the manufacturer of the product with digital elements concerned, add the notified publicly known vulnerability pursuant to paragraph 1 or Article 11 or paragraph 1 or Article 11a to the European vulnerability database referred to and in accordance with Article 12 of Directive (EU) 2022/2555.*
6. *The CSIRTs designated as coordinators shall provide helpdesk support in relation to the reporting obligations under Article 11 to manufacturers and in particular manufacturers that qualify as microenterprises or as small or medium-sized enterprises.*

Article 12

Authorised representatives

1. A manufacturer may, by a written mandate, ***appoint an authorised representative***.
2. The obligations laid down in Article 10(1) to (7) first indent and (9) shall not form part of the authorised representative's mandate.
3. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. ***It shall provide a copy of the mandate to the market surveillance authorities upon request.*** The mandate shall allow the authorised representative to do at least the following:
 - (a) keep the EU declaration of conformity referred to in Article 20 and the technical documentation referred to in Article 23 at the disposal of the market surveillance authorities for ***at least*** ten years after the product with digital elements has been placed on the market, ***or the support period, whichever is longer***;
 - (b) further to a reasoned request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the product with digital elements;
 - (c) cooperate with the market surveillance authorities, at their request, on any action taken to eliminate the risks posed by a product with digital elements covered by the authorised representative's mandate.

Article 13

Obligations of importers

1. Importers shall only place on the market products with digital elements that comply with the essential requirements set out in Section 1 of Annex I and where the processes put in place by the manufacturer are compliant with the essential requirements set out in Section 2 of Annex I.

2. Before placing a product with digital elements on the market, importers shall ensure that:
- (a) the appropriate conformity assessment procedures referred to in Article 24 have been carried out by the manufacturer;
 - (b) the manufacturer has drawn up the technical documentation;
 - (c) the product with digital elements bears the CE marking referred to in Article 22 and is accompanied by the *EU declaration of conformity as referred to in Article 10(11) and the information and instructions for use as set out in Annex II in a language which can be easily understood by users and market surveillance authorities.*
 - (d) *The manufacturer has complied with the requirements set out in Article 10(9a), 10(9b) and 10(10a).*

For the purposes of this paragraph, importers shall be able to provide the necessary documents proving the fulfilment of the requirements set out in this Article.

3. Where an importer considers or has reason to believe that a product with digital elements or the processes put in place by the manufacturer are not in conformity with *this Regulation*, the importer shall not place the product on the market until that product or the processes put in place by the manufacturer have been brought into conformity with *this Regulation*. Furthermore, where the product with digital elements presents a significant cybersecurity risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

Where an importer has reason to believe that a product with digital elements may present a significant cybersecurity risk in light of non-technical risk factors, the importer shall inform the market surveillance authorities to that effect. Upon receipt of such information, the market surveillance authorities shall follow the procedures referred to in Article 43(1a).

4. Importers shall indicate their name, registered trade name or registered trademark, the postal address, ***email address or other digital contact as well as, where applicable, the website*** at which they can be contacted on the product with digital elements or **■** on its packaging or in a document accompanying the product with digital elements. The contact details shall be in a language easily understood by users and market surveillance authorities.

■

5. Importers who know or have reason to believe that a product with digital elements, which they have placed on the market ***is*** not in conformity with ***this Regulation*** shall immediately take the corrective measures necessary to ***ensure that the*** product with digital elements ***is brought*** into conformity **■**, or to withdraw or recall the product, if appropriate.

Upon ***becoming aware of*** a vulnerability in the product with digital elements, importers shall inform the manufacturer without undue delay about that vulnerability. Furthermore, where the product with digital elements presents a significant cybersecurity risk, importers shall immediately inform the market surveillance authorities of the Member States in which they made the product with digital elements available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

6. Importers shall, for ***at least*** ten years after the product with digital elements has been placed on the market ***or for the support period, whichever is longer***, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

7. Importers shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the product with digital elements with the essential requirements set out in Section 1 of Annex I as well as of the processes put in place by the manufacturer with the essential requirements set out in Section 2 of Annex I in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the cybersecurity risks posed by a product with digital elements, which they have placed on the market.

8. When the importer of a product with digital elements becomes aware that the manufacturer of that product ceased its operations and, as result, is not able to comply with the obligations laid down in this Regulation, the importer shall inform the relevant market surveillance authorities about this situation, as well as, by any means available and to the extent possible, the users of the products with digital elements placed on the market.

Article 14

Obligations of distributors

1. When making a product with digital elements available on the market, distributors shall act with due care in relation to the requirements of this Regulation.
2. Before making a product with digital elements available on the market, distributors shall verify that:
 - (a) the product with digital elements bears the CE marking;
 - (b) the manufacturer and the importer have complied with the obligations set out respectively in Articles **10(9a)**, **10(9b)**, 10(10), **10(10a)**, 10(11) and 13(4) **and have communicated all necessary documents to the distributor.**
3. Where a distributor considers or has reason to believe, **on the basis of information in its possession**, that a product with digital elements or the processes put in place by the manufacturer are not in conformity with the essential requirements set out in Annex I, the distributor shall not make the product with digital elements available on the market until that product or the processes put in place by the manufacturer have been brought into conformity. Furthermore, where the product with digital elements poses a significant cybersecurity risk, the distributor shall inform, **without undue delay**, the manufacturer and the market surveillance authorities to that effect.

4. Distributors who know or have reason to believe, *on the basis of information in their possession*, that a product with digital elements, which they have made available on the market, or the processes put in place by its manufacturer are not in conformity with *this Regulation* shall make sure that the corrective measures necessary to bring that product with digital elements or the processes put in place by its manufacturer into conformity are taken, or to withdraw or recall the product, if appropriate.

Upon *becoming aware of* a vulnerability in the product with digital elements, distributors shall inform the manufacturer without undue delay about that vulnerability. Furthermore, where the product with digital elements presents a significant cybersecurity risk, distributors shall immediately inform the market surveillance authorities of the Member States in which they have made the product with digital elements available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the product with digital elements and the processes put in place by its manufacturer with *this Regulation* in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the cybersecurity risks posed by a product with digital elements, which they have made available on the market.
6. When the distributor of a product with digital elements becomes aware, *on the basis of information in its possession*, that the manufacturer of that product ceased its operations and, as result, is not able to comply with the obligations laid down in this Regulation, the distributor shall inform, *without undue delay*, the relevant market surveillance authorities about this situation, as well as, by any means available and to the extent possible, the users of the products with digital elements placed on the market.

Article 15

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to ■ Articles 10 and *II*, where that importer or distributor places a product with digital elements on the market under his or her name or trademark or carries out a substantial modification of the product with digital elements already placed on the market.

Article 16

Other cases in which obligations of manufacturers apply

A natural or legal person, other than the manufacturer, the importer or the distributor, that carries out a substantial modification of the product with digital elements *and makes it available on the market*, shall be considered a manufacturer for the purposes of this Regulation.

That person shall be subject to ■ Articles 10 and *II*, for the part of the product that is affected by the substantial modification or, if the substantial modification has an impact on the cybersecurity of the product with digital elements as a whole, for the entire product.

Article 17

Identification of economic operators

1. Economic operators shall, on request ■ , provide to the market surveillance authorities the following information:
 - (a) name and address of any economic operator who has supplied them with a product with digital elements;
 - (b) name and address of any economic operator to whom they have supplied a product with digital elements, *where the information is available*;

2. Economic operators shall be able to present the information referred to in paragraph 1 for ten years after they have been supplied with the product with digital elements and for ten years after they have supplied the product with digital elements.

Article 17a

Obligations of open-source software stewards

1. *Open-source software stewards shall put in place and document in a verifiable manner a cybersecurity policy to foster the development of a secure product with digital elements as well as an effective handling of vulnerabilities by the developers of that product. It shall also foster the voluntary reporting of vulnerabilities as laid down in Article 11a by the developers of that product. The cybersecurity policy shall take into account the specific nature of the open-source software steward and the legal and organisational arrangements it is subject to. It shall in particular include aspects related to documenting, addressing and remediating vulnerabilities as well as promote the sharing of information concerning discovered vulnerabilities within the open-source community.*
2. *Open-source software stewards shall cooperate with the market surveillance authorities, at their request, with a view to mitigating the cybersecurity risks posed by a product with digital elements qualifying as free and open-source software.*

Further to a reasoned request from a market surveillance authority, open-source software stewards shall provide that authority, in a language which can be easily understood by it, with the documentation referred to in the first paragraph, in paper or electronic form.

3. *The obligations laid down in Article 11, paragraph 1, shall apply to open-source software stewards to the extent that they are involved in the development of the products with digital elements. The obligations laid down in Article 11, paragraphs 3 and 8 shall apply to open-source software stewards to the extent that severe incidents having an impact on the security of products with digital elements affect network and information systems provided by the open-source software stewards for the development of such products.*

Article 17b

Security attestation of free and open-source software

In order to facilitate the due diligence obligation set out in Article 10(4) of this Regulation, in particular as regards manufacturers that integrate free and open-source software components in their products with digital elements, the Commission is empowered to adopt delegated acts in accordance with Article 50 to supplement this Regulation by establishing voluntary security attestation programmes allowing the developers or users of products with digital elements qualifying as free and open-source software as well as other third-parties to assess the conformity of such products with all or certain essential requirements or other obligations laid down in this Regulation.

Article 17c

Guidance

- 1. In order to facilitate the implementation of this Regulation and ensure consistency, the Commission shall publish guidance to assist the economic operators in applying this Regulation, with a particular focus on how to facilitate compliance by microenterprises, small enterprises and medium-sized enterprises.*
- 2. The Commission, where it intends to provide guidelines, shall address at least the following aspects:*
 - (a) the scope of this Regulation, with a particular focus on remote data processing solutions and free and open-source software;*
 - (b) the notion of the support period in relation to different product categories;*
 - (c) guidance targeted at manufacturers subject to this Regulation who are also subject to other related Union harmonisation legislation or other related Union acts;*
 - (d) the notion of substantial modifications.*

The Commission shall also maintain an easy-to-access list of the delegated and implementing acts published pursuant to this Regulation.

3. *When preparing the guidance pursuant to this Article, the Commission shall consult relevant stakeholders.*

CHAPTER III
Conformity of the product with digital elements

Article 18
Presumption of conformity

1. Products with digital elements and processes put in place by the manufacturer which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential requirements *set out in Annex I* covered by those standards or parts thereof.

The Commission shall, in accordance with Article 10(1) of Regulation (EU) 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential requirements set out in Annex I to this Regulation. When preparing the standardisation request for this Regulation, the Commission shall strive to take into account existing international and European standards for cybersecurity that are in place or under development in order to simplify the development of harmonised standards, in line with Regulation (EU) 1025/2012.

2. *The Commission may adopt implementing acts establishing common specifications covering technical requirements that provide a means to comply with the essential requirements set out in Annex I for products with digital elements within the scope of this Regulation.*

Those implementing acts shall only be adopted where the following conditions are fulfilled:

- (a) *the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential requirements set out in Annex I and:*
 - (i) *the request has not been accepted; or*

8. *When a Member State considers that a common specification does not entirely satisfy the essential requirements set out in Annex I, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.*
9. Products with digital elements and processes put in place by the manufacturer for which an EU statement of conformity or certificate has been issued under a European cybersecurity certification scheme adopted as per Regulation (EU) 2019/881 ■, shall be presumed to be in conformity with the essential requirements set out in Annex I in so far as the EU statement of conformity or cybersecurity certificate, or parts thereof, cover those requirements.
10. The Commission is empowered *to adopt delegated acts in accordance with Article 50 to supplement this Regulation by specifying* the European cybersecurity certification schemes adopted pursuant to Regulation (EU) 2019/881 that can be used to demonstrate conformity *of products with digital elements* with the essential requirements or parts thereof as set out in Annex I. Furthermore, *the issuance of* a cybersecurity certificate issued under such schemes, *at assurance level at least substantial*, eliminates the obligation of a manufacturer to carry out a third-party conformity assessment for the corresponding requirements, as set out in Article 24(2)(a), (b), (3)(a) and (b). ■

■

Article 20

EU declaration of conformity

1. The EU declaration of conformity shall be drawn up by manufacturers in accordance with Article 10(7) and state that the fulfilment of the applicable essential requirements set out in Annex I has been demonstrated.
2. The EU declaration of conformity shall have the model structure set out in Annex IV and shall contain the elements specified in the relevant conformity assessment procedures set out in Annex VI. Such a declaration shall be updated *as appropriate*. It shall be made available in the language or languages required by the Member State in which the product with digital elements is placed on the market or made available *on the market*.

The simplified EU declaration of conformity referred to in Article 10(11) shall contain the model structure set out in Annex IVa. It shall be made available in the languages required by the Member State in which the product with digital elements is placed on the market or made available on the market.

3. Where a product with digital elements is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.
4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product.
5. The Commission is empowered to adopt delegated acts in accordance with Article 50 to supplement this Regulation by adding elements to the minimum content of the EU declaration of conformity set out in Annex IV to take account of technological developments.

Article 21
General principles of the CE marking

The CE marking as defined in Article 3(32) shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article 22
Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the product with digital elements. Where that is not possible or not warranted on account of the nature of the product with digital elements, it shall be affixed to the packaging and to the EU declaration of conformity referred to in Article 20 accompanying the product with digital elements. For products with digital elements which are in the form of software, the CE marking shall be affixed either to the EU declaration of conformity referred to in Article 20 or on the website accompanying the software product. ***In the latter case, the relevant section of the website shall be easily and directly accessible to consumers.***
2. On account of the nature of the product with digital elements, the height of the CE marking affixed to the product with digital elements may be lower than 5 mm, provided that it remains visible and legible.
3. The CE marking shall be affixed before the product with digital elements is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use set out in implementing acts referred to in paragraph 6.
4. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the conformity assessment procedure based on full quality assurance (based on module H) referred to in Article 24.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.

5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking. Where the product with digital elements is subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the product also fulfils the requirements of that other legislation.
6. The Commission may, by means of implementing acts, lay down technical specifications for *labels*, pictograms or any other marks related to the security of the products with digital elements, *their support period* and mechanisms to promote their use *and to increase public awareness about the security of products with digital elements*. *When preparing the draft implementing act, the Commission shall consult relevant stakeholders, and, if it has already been established pursuant to Article 41(11), the dedicated administrative cooperation group (ADCO)*. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).

Article 23

Technical documentation

1. The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that the product with digital elements and the processes put in place by the manufacturer comply with the essential requirements set out in Annex I. It shall at least contain the elements set out in Annex V.
2. The technical documentation shall be drawn up before the product with digital elements is placed on the market and shall be continuously updated, where appropriate, during *at least the support period* .
3. For products with digital elements referred to in Articles 8 and 24(4) that are also subject to other Union acts, one single technical documentation shall be drawn up containing the information referred to in Annex V of this Regulation and the information required by those respective Union acts.
4. The technical documentation and correspondence relating to any conformity assessment procedure shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.

5. The Commission is empowered to adopt delegated acts in accordance with Article 50 to supplement this Regulation by the elements to be included in the technical documentation set out in Annex V to take account of technological developments, as well as developments encountered in the implementation process of this Regulation. ***For this purpose, the Commission shall strive to ensure that the administrative burden on microenterprises and small and medium-sized enterprises is proportionate.***

Article 24

Conformity assessment procedures for products with digital elements

1. The manufacturer shall perform a conformity assessment of the product with digital elements and the processes put in place by the manufacturer to determine whether the essential requirements set out in Annex I are met. The manufacturer **■** shall demonstrate conformity with the essential requirements by using ***any*** of the following procedures:
- (a) the internal control procedure (based on module A) set out in Annex VI; **■**
 - (b) the EU-type examination procedure (based on module B) set out in Annex VI followed by conformity to EU-type based on internal production control (based on module C) set out in Annex VI; **■**
 - (c) conformity assessment based on full quality assurance (based on module H) set out in Annex VI; ***or***
 - (d) ***where available and applicable, a European cybersecurity certification scheme as specified in Article 18(10).***

2. Where, in assessing the compliance of the **important** product with digital elements of class I as set out in Annex III and the processes put in place by its manufacturer with the essential requirements set out in Annex I, the manufacturer ■ has not applied or has applied only in part harmonised standards, common specifications or European cybersecurity certification schemes **at assurance level at least substantial** as referred to in Article 18, or where such harmonised standards, common specifications or European cybersecurity certification schemes do not exist, the product with digital elements concerned and the processes put in place by the manufacturer shall be submitted with regard to those essential requirements to **any** of the following procedures:
- (a) **the** EU-type examination procedure (based on module B) **set out** in Annex VI followed by conformity to EU-type based on internal production control (based on module C) set out in Annex VI; or
 - (b) conformity assessment based on full quality assurance (based on module H) set out in Annex VI.
3. Where the product is an **important** product with digital elements of class II as set out in Annex III, the manufacturer ■ shall demonstrate conformity with the essential requirements set out in Annex I by using **any** of the following procedures:
- (a) EU-type examination procedure (based on module B) set out in Annex VI followed by conformity to EU-type based on internal production control (based on module C) set out in Annex VI; ■
 - (b) conformity assessment based on full quality assurance (based on module H) set out in Annex VI; **or**
 - (c) **where available and applicable, a European cybersecurity certification scheme as specified in Article 18(10) at assurance level at least substantial pursuant to Regulation (EU) 2019/881.**

- 3a. *Critical products with digital elements listed in Annex IIIa shall demonstrate conformity with the essential requirements set out in Annex I by using one of the following procedures:*
- (a) *a European cybersecurity certification scheme in accordance with Article 6a(1),*
or,
 - (b) *where the conditions in Article 6a(1) are not met, any of the procedures referred to in paragraph 3 of this Article.*
- 3b. *Manufacturers of products with digital elements qualifying as free and open-source software, which fall under the categories listed in Annex III to this Regulation, shall be able to demonstrate conformity with the essential requirements set out in Annex I by using one of the procedures referred to in paragraph 1, provided that the technical documentation referred to in Article 23 is made available to the public at the time of the placing on the market of those products.*
4. Manufacturers of products with digital elements that are classified as EHR systems under Regulation [the European Health Data Space Regulation] shall demonstrate conformity with the essential requirements laid down in Annex I of this Regulation using the relevant conformity assessment procedure as required by Regulation [Chapter III of the European Health Data Space Regulation]³³.
5. The specific interests and needs of *microenterprises and* small and *medium-sized* enterprises, *including start-ups, shall be taken into account* when setting the fees for conformity assessment procedures and those fees *shall be reduced* proportionately to their specific interests and needs.

³³ *Technical note: the co-legislators have decided that this provision should be deleted if the planning for adoption and publication of the European Health Data Space Regulation (2022/0140(COD)) is significantly longer than the one of the Cyber Resilience Act (2022/0272(COD)), and will be introduced as an amendment through the European Health Data Space Regulation.*

Article 24a

Support measures for micro, small and medium-sized enterprises, including start-ups

1. *Member States shall, where appropriate, undertake the following actions, tailored to the needs of micro and small enterprises:*
 - (a) *organise specific awareness raising and training activities about the application of this Regulation;*
 - (b) *establish a dedicated channel for communication with micro and small enterprises and, as appropriate, local public authorities to provide advice and respond to queries about the implementation of this Regulation;*
 - (c) *support testing and conformity assessment activities, including where relevant with the support of the European Cybersecurity Competence Center.*

2. *Member States may, where appropriate, establish cyber resilience regulatory sandboxes. Such regulatory sandboxes shall provide for controlled testing environments for innovative products with digital elements to facilitate their development, design, validation and testing in view of complying with this Regulation for a limited period of time before the placement of the market. The Commission, and where appropriate ENISA, may provide technical support, advice and tools for the establishment and operation of regulatory sandboxes. The regulatory sandboxes shall be set up under the direct supervision, guidance and support by the market surveillance authorities. Member States shall inform the Commission and the other market surveillance authorities of the establishment of a regulatory sandbox through the ADCO. The regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Member States shall ensure open, fair, and transparent access to regulatory sandboxes, and in particular facilitate the access for micro and small enterprises, including start-ups.*

3. *In accordance with Article 17c, the Commission shall ensure the development of guidance for micro, small and medium-sized enterprises in relation to the implementation of this Regulation.*

4. *The Commission shall advertise available financial support in the regulatory framework of existing Union programmes, in particular in order to ease the financial burden on micro and small enterprises.*
5. *Micro and small enterprises may provide all elements of the technical documentation specified in Annex V by using a simplified format. For this purpose, the Commission shall, by means of implementing acts, specify the simplified technical documentation form targeted at the needs of micro and small enterprises, including how the elements of Annex V are to be provided. Where a micro or small enterprise opts to provide the information required in Annex V in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purpose of conformity assessment.*

The implementing acts referred to in this paragraph shall be adopted in accordance with the examination procedure referred to in Article 51(2).

Article 24b

Mutual recognition agreements

Taking into account the level of technical development and the approach on conformity assessment of a third country, the Union may conclude Mutual Recognition Agreements with such third countries, in order to promote and facilitate international trade.

CHAPTER IV
NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 25
Notification

Member States shall notify the Commission and the other Member States of **■** bodies authorised to carry out conformity assessments in accordance with this Regulation.

Article 26
Notifying authorities

1. 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, including compliance with Article 31.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. ***Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 27 of this Regulation. In addition, it shall have arrangements to cover liabilities arising out of its activities.***
4. ***The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.***

Article 27

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organised and shall function so as to safeguard the objectivity and impartiality of its activities.
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 28

Information obligation on notifying authorities

1. Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.
 - 1a. *Member States shall strive to, by... [24 months from the date of entry into force of this Regulation], ensure that there is a sufficient number of notified bodies in the Union to carry out conformity assessments, in order to avoid bottlenecks and hindrances to market entry.***
2. The Commission shall make ***the*** information ***referred to in paragraph 1*** publicly available.

Article 29

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 12.
2. A conformity assessment body shall be established under national law and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, development, production, provision, assembly, use or maintenance of products with digital elements which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, developer, manufacturer, supplier, **importer, distributor**, installer, purchaser, owner, user or maintainer of the products with digital elements which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, development, production, **import, distribution**, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks referred to in Annex VI and in relation to which it has been notified, regardless of whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of products with digital elements in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) *personnel* with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment activities shall have the following:
- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - (c) appropriate knowledge and understanding of the essential requirements *set out in Annex I*, of the applicable harmonised standards *as well as the common specifications* and of the relevant provisions of Union harmonisation legislation and of its implementing acts;
 - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.
- The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.
9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex VI or any provision of national law giving effect to it, except in relation to the market surveillance authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected. The conformity assessment body shall have documented procedures ensuring compliance with this paragraph.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 40 and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.
12. Conformity assessment bodies shall operate in accordance with a set of consistent, fair, *proportionate* and reasonable terms and conditions, *while avoiding unnecessary burdens for economic operators*, in particular taking into account the interests of *microenterprises and small and medium-sized enterprises* in relation to fees.

Article 30

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in Article 29 in so far as the applicable harmonised standards cover those requirements.

Article 31

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 29 and shall inform the notifying authority accordingly.
2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the manufacturer.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

Article 32

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment procedure or procedures and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where *applicable*, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 29.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 29.

Article 33

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies, which have satisfied the requirements laid down in Article 29.
2. The notifying authority shall notify the Commission and the other Member States using the New Approach Notified and Designated Organisations (NANDO) information system developed and managed by the Commission.
3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and product or products concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 32(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 29.
5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Regulation.
6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 34

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.
2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that that list is kept up to date.

Article 35
Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 29, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 36
Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.
2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article 37

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Article 24 and Annex VI.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, ***with consideration for microenterprises and small and medium-sized enterprises***, the sector in which it operates, its structure, the degree of complexity ***and the cybersecurity risk level*** of the product ***and*** technology in question and the mass or serial nature of the production process.
3. Notified bodies shall however respect the degree of rigour and the level of protection required for the compliance of the product with the provisions of Regulation.
4. Where a notified body finds that requirements laid down in Annex I or in corresponding harmonised standards or in common specifications as referred to in Article **18** have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a **■** certificate ***of conformity***.
5. Where, in the course of the monitoring of conformity following the issuance of a certificate, a notified body finds that a product no longer complies with the requirements laid down in this Regulation, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
6. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 37a
Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

Article 38
Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:
 - (a) any refusal, restriction, suspension or withdrawal of a certificate;
 - (b) any circumstances affecting the scope of and conditions for notification;
 - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
 - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
2. Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 39
Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 40

Coordination of notified bodies

1. The Commission shall ensure that appropriate coordination and cooperation between notified bodies are put in place and properly operated in the form of a cross-sectoral group of notified bodies.
2. Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

CHAPTER V
MARKET SURVEILLANCE AND ENFORCEMENT

Article 41

Market surveillance and control of products with digital elements in the Union market

1. Regulation (EU) 2019/1020 shall apply to the products with digital elements within the scope of this Regulation.
 - 1a. ***The market surveillance authorities designated under paragraph 2 of this Article shall also be responsible for carrying out market surveillance activities in relation to the obligations placed on open-source software stewards in Article 17a of this Regulation. Where a market surveillance authority finds that an open-source software steward is not compliant with the obligations set out in that article, it shall require the open-source software steward to ensure that all appropriate corrective actions are taken. Open-source software stewards shall ensure that all appropriate corrective action is taken in respect of their obligations under this Regulation.***
2. Each Member State shall designate one or more market surveillance authorities for the purpose of ensuring the effective implementation of this Regulation. Member States may designate an existing or new authority to act as market surveillance authority for this Regulation.
3. Where relevant, the market surveillance authorities shall cooperate with the national cybersecurity certification authorities designated under Article 58 of Regulation (EU) 2019/881 and exchange information on a regular basis. With respect to the supervision of the implementation of the reporting obligations pursuant to Article 11 of this Regulation, the designated market surveillance authorities shall cooperate ***and exchange information on a regular basis with the CSIRTs designated as coordinators and ENISA.***

- 3a. *The market surveillance authorities may request the CSIRT designated as coordinator or ENISA to provide technical advice on matters related to the implementation and enforcement of this Regulation. When conducting an investigation under Article 43, market surveillance authorities may request the CSIRT designated as coordinator or ENISA to provide an analysis to support evaluations of compliance of products with digital elements.*
4. Where relevant, the market surveillance authorities shall cooperate with other market surveillance authorities designated on the basis of other Union harmonisation legislation for other products, and exchange information on a regular basis.
5. Market surveillance authorities shall cooperate, as appropriate, with the authorities supervising Union data protection law. Such cooperation includes informing these authorities of any finding relevant for the fulfilment of their competences, including when issuing guidance and advice pursuant to paragraph 8 of this Article if such guidance and advice concerns the processing of personal data.
- Authorities supervising Union data protection law shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of their tasks. They shall inform the designated market surveillance authorities of the Member State concerned of any such request.
6. Member States shall ensure that the designated market surveillance authorities are provided with adequate financial and *technical resources, including, where appropriate, processing automation tools, as well as with* human resources *with the necessary cybersecurity skills* to fulfil their tasks under this Regulation.
7. The Commission shall *encourage and* facilitate the exchange of experience between designated market surveillance authorities.
8. Market surveillance authorities may provide guidance and advice to economic operators on the implementation of this Regulation, with the support of the Commission, *and where appropriate CSIRTs and ENISA.*

- 8a. *Market surveillance authorities shall inform consumers of where to submit complaints that might indicate non-compliance with this Regulation, in accordance with Article 11 of Regulation 2019/1020, and also provide information to consumers on where and how to access mechanisms to facilitate reporting of vulnerabilities, incidents and cyber threats that may affect products with digital elements.*
9. The market surveillance authorities shall report to the Commission on an annual basis the outcomes of relevant market surveillance activities. The designated market surveillance authorities shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union competition law.
10. For products with digital elements *that fall within* the scope of this Regulation classified as high-risk AI systems according to Article [Article 6] of the Regulation [the AI Regulation]³⁴, the market surveillance authorities designated for the purposes of the Regulation [the AI Regulation] shall be the authorities responsible for market surveillance activities required under this Regulation. The market surveillance authorities designated pursuant to Regulation [the AI Regulation] shall cooperate, as appropriate, with the market surveillance authorities designated pursuant to this Regulation and, with respect to the supervision of the implementation of the reporting obligations pursuant to Article 11, with *the CSIRTs designated as coordinators and* ENISA. Market surveillance authorities designated pursuant to Regulation [the AI Regulation] shall in particular inform market surveillance authorities designated pursuant to this Regulation of any finding relevant for the fulfilment of their tasks in relation to the implementation of this Regulation.

³⁴ *Technical note: the co-legislators have decided that this provision should be deleted if the planning for adoption and publication of the Artificial Intelligence Act (2021/0106(COD)) is significantly longer than the one of the Cyber Resilience Act (2022/0272(COD)), and will be introduced as an amendment through the Artificial Intelligence Act.*

11. A dedicated administrative cooperation group (ADCO) shall be established for the uniform application of this Regulation, pursuant to Article 30(2) of Regulation (EU) 2019/1020. This ADCO shall be composed of representatives of the designated market surveillance authorities and, if appropriate, representatives of single liaison offices. ***The ADCO shall also address specific matters related to the market surveillance activities in relation to the obligations placed on open-source software stewards.***

11a. Market surveillance authorities shall monitor how manufacturers have applied the criteria referred to in Article 10(6) when determining the support period of their products with digital elements.

ADCO shall publish in a publicly accessible and user-friendly manner relevant statistics on categories of products with digital elements, including their average support period, as specified by the manufacturer pursuant to Article 10(10a), as well as provide guidance that includes indicative support periods for categories of products with digital elements.

Where the data may suggest inadequate support periods for specific categories of products with digital elements, ADCO may issue recommendations to market surveillance authorities to focus their activities on such categories of products with digital elements.

11b. Market surveillance authorities shall facilitate, where relevant, the cooperation with relevant stakeholders, including scientific, research and consumer organisations.

Article 42

Access to data and documentation

Where necessary to assess the conformity of products with digital elements and the processes put in place by their manufacturers with the essential requirements set out in Annex I and upon a reasoned request, the market surveillance authorities shall be granted access to the data, ***in a language easily understood by them***, required to assess the design, development, production and vulnerability handling of such products, including related internal documentation of the respective economic operator.

Article 43

Procedure at national level concerning products with digital elements presenting a significant cybersecurity risk

1. Where the market surveillance authority of a Member State has sufficient ***reason*** to consider that a product with digital elements, including its vulnerability handling, presents a significant cybersecurity risk, it shall carry out, ***without undue delay and where appropriate in cooperation with the CSIRT***, an evaluation of the product with digital elements concerned in respect of its compliance with all the requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authority.

Where, in the course of that evaluation, the market surveillance authority finds that the product with digital elements does not comply with the requirements laid down in this Regulation, it shall without delay require the relevant ***economic*** operator to take all appropriate corrective actions to bring the product ***with digital elements*** into compliance with those requirements, to withdraw it from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as ***the market surveillance authority*** may prescribe.

The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the **■** corrective actions.

- 1a.** *When determining the significance of a cybersecurity risk referred to in paragraph 1, the market surveillance authorities shall also consider non-technical risk factors, in particular those established as a result of Union level coordinated security risk assessments of critical supply chains in accordance with Article 22 of Directive (EU) 2022/2555. Where a market surveillance authority has sufficient reason to consider that a product with digital elements presents a significant cybersecurity risk in light of non-technical risk factors, it shall inform the competent authorities designated or established in accordance with Article 8 of Directive (EU) 2022/2555 and cooperate with these authorities as necessary.*
2. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the *economic* operator to take.
3. The *economic operator* shall ensure that all appropriate corrective action is taken in respect of all the products with digital elements concerned that it has made available on the market throughout the Union.
4. Where the *economic operator* does not take adequate corrective action within the period referred to in paragraph 1, second subparagraph, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict that product *with digital elements from* being made available on its national market, to withdraw it from that market or to recall it.

That authority shall *notify* the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant **product** with digital elements, the origin of **that** product with digital elements, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant **economic** operator. In particular, the market surveillance authority shall indicate whether the non-compliance is due to one or more of the following:
- (a) a failure of the product **with digital elements** or of the processes put in place by the manufacturer to meet the essential requirements set out in Annex I;
 - (b) shortcomings in the harmonised standards, cybersecurity certification schemes, or common specifications, referred to in Article 18.
6. The market surveillance authorities of the Member States other than the market surveillance authority of the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product **with digital elements** concerned, and, in the event of disagreement with the notified national measure, of their objections.
7. Where, within three months of receipt of the **notification** referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of the **economic** operator concerned in accordance with Article 18 of Regulation (EU) 2019/1020.
8. The market surveillance authorities of all Member States shall ensure that appropriate restrictive measures are taken in respect of the product **with digital elements** concerned, such as withdrawal of **that** product from their market, without delay.

Article 44
Union safeguard procedure

1. Where, within three months of receipt of the notification referred to in Article 43(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union *law*, the Commission shall without delay enter into consultation with the relevant Member State and the economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within nine months from the notification referred to in Article 43(4) and notify *that* decision to the Member State concerned.
2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant product with digital elements is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.
3. Where the national measure is considered justified and the non-compliance of the product with digital elements is attributed to shortcomings in the harmonised standards, the Commission shall apply the procedure provided for in Article *11* of Regulation (EU) No 1025/2012.
4. Where the national measure is considered justified and the non-compliance of the product with digital elements is attributed to shortcomings in a European cybersecurity certification scheme as referred to in Article 18, the Commission shall consider whether to amend or repeal the *delegated* act as referred to in Article 18(*10*) that specifies the presumption of conformity concerning that certification scheme.
5. Where the national measure is considered justified and the non-compliance of the product with digital elements is attributed to shortcomings in common specifications as referred to in Article *18*, the Commission shall consider whether to amend or repeal the implementing act referred to in Article *18* setting out those common specifications.

Article 45

Procedure at EU level concerning products with digital elements presenting a significant cybersecurity risk

1. Where the Commission has sufficient **reason** to consider, including based on information provided by ENISA, that a product with digital elements that presents a significant cybersecurity risk is non-compliant with the requirements laid down in this Regulation, it **shall inform** the relevant market surveillance authorities. **Where the market surveillance authorities** carry out an evaluation of **that product with digital elements that may present a significant cybersecurity risk in respect of its compliance with the requirements laid down in this Regulation**, the procedures referred to in **Articles 43 and 44 shall apply**.
 - 1a. **Where the Commission has sufficient reason to consider that a product with digital elements presents a significant cybersecurity risk in light of non-technical risk factors, it shall inform the relevant market surveillance authorities and, where appropriate, the competent authorities designated or established in accordance with Article 8 of Directive (EU) 2022/2555 and cooperate with these authorities as necessary. The Commission shall also consider the relevance of the identified risks for that product with digital elements in view of its tasks regarding the Union level coordinated security risk assessments of critical supply chains provided for in Article 22 of Directive (EU) 2022/2555 and consult as necessary the Cooperation Group established in accordance with Article 14 of Directive (EU) 2022/2555 and ENISA.**
2. In **■** circumstances which justify an immediate intervention to preserve the good functioning of the internal market and where the Commission has sufficient reasons to consider that the product **with digital elements** referred to in paragraph 1 remains non-compliant with the requirements laid down in this Regulation and no effective measures have been taken by the relevant market surveillance authorities, the Commission **shall carry out an evaluation of compliance and** may request ENISA to **provide an analysis to support it**. The Commission shall inform the relevant market surveillance authorities accordingly. The relevant economic operators shall cooperate as necessary with ENISA.

3. Based on *the* evaluation *referred to in paragraph 2*, the Commission may decide that a corrective or restrictive measure is necessary at Union level. To this end, it shall without delay consult the Member States concerned and the relevant economic operator or operators.
4. On the basis of the consultation referred to in paragraph 3, the Commission may adopt implementing acts to decide on corrective or restrictive measures at Union level, including ordering withdrawal *of the product with digital elements* from the market, or recalling *of it*, within a reasonable period, commensurate with the nature of the risk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).
5. The Commission shall immediately communicate the *implementing acts* referred to in paragraph 4 to the relevant economic operator or operators. Member States shall implement *those* acts without delay and shall inform the Commission accordingly.
6. Paragraphs 2 to 5 are applicable for the duration of the exceptional situation that justified the Commission's intervention and for as long as the product *with digital elements concerned* is not brought in compliance with this Regulation.

Article 46

Compliant products with digital elements which present a significant cybersecurity risk

1. **█** The market surveillance authority of a Member State *shall require an economic operator to take all appropriate measures where, having performed an evaluation under Article 43, it finds that although a product with digital elements and the processes put in place by the manufacturer are in compliance with this Regulation, it presents a significant cybersecurity risk as well as a risk to:*
 - (a) *the health or safety of persons;*
 - (b) *the compliance with obligations under Union or national law intended to protect fundamental rights;*

(c) *the availability, authenticity, integrity or confidentiality of services offered using an electronic information system by essential entities of a type referred to in Article 3 of Directive (EU) 2022/2555; or*

(d) *other aspects of public interest protection.*

The measures referred to in the first subparagraph may include measures to ensure that the product with digital elements concerned and the processes put in place by the manufacturer no longer present the relevant risks when made available on the market, withdrawal from the market of the product with digital elements concerned, or recalling of it, and shall be commensurate with the nature of those risks.

2. The manufacturer or other relevant *economic* operators shall ensure that corrective action is taken in respect of the products with digital elements concerned that they have made available on the market throughout the Union within the timeline established by the market surveillance authority of the Member State referred to in paragraph 1.
3. The Member State shall immediately inform the Commission and the other Member States about the measures taken pursuant to paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the products with digital elements concerned, the origin and the supply chain of those products with digital elements, the nature of the risk involved and the nature and duration of the national measures taken.
4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.
5. The Commission shall address its decision to the Member States.
6. Where the Commission has sufficient *reason* to consider, including based on information provided by ENISA, that a product with digital elements, although compliant with this Regulation, presents the risks referred to in paragraph 1, it ***shall inform and*** may request the relevant market surveillance authority or authorities to carry out an evaluation **■** and follow the procedures referred to in Article 43 and paragraphs 1, 2 and 3 of this Article.

7. In **■** circumstances which justify an immediate intervention to preserve the good functioning of the internal market and where the Commission has sufficient reasons to consider that the product *with digital elements* referred to in paragraph 6 continues to present the risks referred to in paragraph 1, and no effective measures have been taken by the relevant national market surveillance authorities, the Commission *shall* carry out an evaluation of the risks presented by that product *with digital elements and may request ENISA to provide an analysis to support that evaluation* and shall inform the relevant market surveillance authorities accordingly. The relevant economic operators shall cooperate as necessary with ENISA.
8. Based on *the* evaluation referred to in paragraph 7, the Commission may establish that a corrective or restrictive measure is necessary at Union level. To this end, it shall without delay consult the Member States concerned and the relevant *economic* operator or operators.
9. On the basis of the consultation referred to in paragraph 8, the Commission may adopt implementing acts to decide on corrective or restrictive measures at Union level, including ordering withdrawal *of the product with digital elements* from the market, or recalling *of it*, within a reasonable period, commensurate with the nature of the risk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).
10. The Commission shall immediately communicate the *implementing acts* referred to in **■** paragraph 9 to the relevant *economic* operator or operators. Member States shall implement *those* acts without delay and shall inform the Commission accordingly.
11. Paragraphs 6 to 10 shall apply for the duration of the exceptional situation that justified the Commission's intervention and for as long as the *product with digital elements concerned* continues to present the risks referred to in paragraph 1.

Article 47

Formal non-compliance

1. Where the market surveillance authority of a Member State makes one of the following findings, it shall require the relevant manufacturer to end to the non-compliance concerned:
 - (a) the **CE** marking has been affixed in violation of Articles 21 and 22;
 - (b) the **CE** marking has not been affixed;
 - (c) the EU declaration of conformity has not been drawn up;
 - (d) the EU declaration of conformity has not been drawn up correctly;
 - (e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;
 - (f) the technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product with digital elements from being made available on the market or ensure that it is recalled or withdrawn from the market.

Article 48

Joint activities of market surveillance authorities

1. Market surveillance authorities may agree with other relevant authorities to carry out joint activities aimed at ensuring cybersecurity and protection of consumers with respect to specific products with digital elements placed **on the market** or made available on the market, in particular products **with digital elements** that are often found to present cybersecurity risks.
2. The Commission or ENISA **shall** propose joint activities for checking compliance with this Regulation to be conducted by market surveillance authorities based on indications or information of potential non-compliance across several Member States of products **with digital elements that fall within** the scope of this Regulation with the requirements laid down by the latter.
3. The market surveillance authorities and **■**, where applicable, **the Commission**, shall ensure that the agreement to carry out joint activities does not lead to unfair competition between economic operators and does not negatively affect the objectivity, independence and impartiality of the parties to the agreement.
4. A market surveillance authority may use any information resulting from the **joint** activities carried out as part of any investigation that it undertakes.
5. The market surveillance authority concerned and, **where applicable, the Commission**, shall make the agreement on joint activities, including the names of the parties involved, available to the public.

Article 49

Sweeps

1. Market surveillance authorities **shall** conduct simultaneous coordinated control actions (“sweeps”) of particular products with digital elements or categories thereof to check compliance with or to detect infringements to this Regulation. **They may include inspections of products acquired under a cover identity.**
2. Unless otherwise agreed upon by the market surveillance authorities involved, sweeps shall be coordinated by the Commission. The coordinator of the sweep **shall**, where appropriate, make the aggregated results publicly available.
3. **Where**, in the performance of its tasks, including based on the notifications received according to Article 11(1) and (3), **ENISA identifies** categories of products **with digital elements** for which sweeps may be organised, **it shall submit a proposal for a sweep** to the **coordinator** referred to in paragraph 2 **of this Article** for the consideration of the market surveillance authorities.
4. When conducting sweeps, the market surveillance authorities involved may use the investigation powers set out **in** Articles 41 to 47 and any other powers conferred upon them by national law.
5. Market surveillance authorities may invite Commission officials, and other accompanying persons authorised by the Commission, to participate in sweeps.

CHAPTER VI
DELEGATED POWERS AND COMMITTEE PROCEDURE

Article 50

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 2(4), Article 6(2), Article **6a(1)**, Article **6a(2)**, Article **10(6)**, Article **11(9) second subparagraph**, Article **17b**, Article **18(10)**, Article 20(5) and Article 23(5) shall be conferred on the Commission **for a period of five years from ... [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**
3. The delegation of power referred to in Article 2(4), Article 6(2), Article **6a(1)**, Article **6a(2)**, Article **10(6)**, Article **11(9) second subparagraph**, Article **17b**, Article **18(10)**, Article 20(5) and Article 23(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with principles laid down in the **Interinstitutional** Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 2(4), Article 6(2), Article *6a(1)*, *Article 6a(2)*, *Article 10(6)*, *Article 11(9) second subparagraph*, Article *17b*, *Article 18(10)*, Article 20(5) and Article 23(5) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 51

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a committee member so requests.

CHAPTER VII
CONFIDENTIALITY AND PENALTIES

Article 52
Confidentiality

1. All parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:
 - (a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 of the European Parliament and of the Council³⁵;
 - (b) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;
 - (c) public and national security interests;
 - (d) integrity of criminal or administrative proceedings.
2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the market surveillance authorities and between market surveillance authorities and the Commission shall not be disclosed without the prior agreement of the originating market surveillance authority.
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law of the Member States.

³⁵ Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

4. The Commission and Member States may exchange, where necessary, sensitive information with relevant authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of protection.

Article 53

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements, **■** of this Regulation, and shall take all measures necessary to ensure that they are *implemented*. The penalties provided for shall be effective, proportionate and dissuasive. ***Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.***

■

3. The non-compliance with the essential cybersecurity requirements laid down in Annex I and the obligations set out in Articles 10 and 11 shall be subject to administrative fines of up to 15 000 000 EUR or, if the offender is an undertaking, up to 2.5 % of the its total worldwide annual turnover for the preceding financial year, whichever is higher.
4. The non-compliance with ***the obligations set out in Articles 12; 13; 14; 15; 16; 17; 20; 22 (1)-(4); 23 (1)-(4); 24(1)-(3); 24a(3) 29; 31; 37; 38; 42*** under this Regulation shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is an undertaking, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.
5. The supply of incorrect, incomplete or misleading information to notified bodies and market surveillance authorities in reply to a request shall be subject to administrative fines of up to 5 000 000 EUR or, if the offender is an undertaking, up to 1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

6. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:
 - (a) the nature, gravity and duration of the infringement and of its consequences;
 - (b) whether administrative fines have been already applied by *the same or* other market surveillance authorities to the same *economic* operator for a similar infringement;
 - (c) the size, *in particular with regard to microenterprises, small and medium sized-enterprises, including start-ups*, and market share of the *economic* operator committing the infringement.
7. Market surveillance authorities that apply administrative fines shall *communicate this to* the market surveillance authorities of other Member States through the information and communication system referred to in Article 34 of Regulation (EU) 2019/1020.
8. Each Member State shall lay down rules on whether and to what extent administrative fines may be imposed on public authorities and *public* bodies established in that Member State.
9. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts or other bodies according to the competences established at national level in those Member States. The application of such rules in those Member States shall have an equivalent effect.
10. Administrative fines may be imposed, depending on the circumstances of each individual case, in addition to any other corrective or restrictive measures applied by the market surveillance authorities for the same infringement.

10a. *By way of derogation from paragraphs 3 to 10 of this Article, the administrative fines referred to in those paragraphs shall not apply to the following:*

- a) manufacturers that qualify as microenterprises or as small enterprises with regard to any failure to meet the deadlines referred to in Article 11(2), point (a), or Article 11(4), point (a);*
- b) any infringement of this Regulation by open-source software stewards.*

CHAPTER VIII
TRANSITIONAL AND FINAL PROVISIONS

Article 54

Amendment to Regulation (EU) 2019/1020

In Annex I to Regulation (EU) 2019/1020 the following point is added:

’71. [Regulation XXX][Cyber Resilience Act].’

Article 54a

Representative actions

Directive (EU) 2020/1828 shall apply to the representative actions brought against infringements by economic operators of provisions of this Regulation that harm, or may harm, the collective interests of consumers.’

Article 54b

Amendment to Directive (EU) 2020/1828

In Annex I to Directive (EU) 2020/1828 of the European Parliament and of the Council³⁶ the following point is added:

’67. [Regulation XXX] [Cyber Resilience Act].’

³⁶ *Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).*

Article 54c
Amendment to Regulation (EU) 168/2013

Annex II to Regulation (EU) 168/2013 is amended as follows:

In Part C, in the table, the following entry is added:

[OP Please insert the next consecutive number under heading C1]	18	Protection of vehicle against cyberattacks		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
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Article 55

Transitional provisions

1. EU type-examination certificates and approval decisions issued regarding cybersecurity requirements for products with digital elements that are subject to other Union harmonisation legislation shall remain valid ... [42 months *from* the date of entry into force of this Regulation], unless they expire before that date, or unless otherwise specified in other Union legislation, in which case they shall remain valid as referred to in that Union legislation.
2. Products with digital elements that have been placed on the market before ... [date of application of this Regulation referred to in Article 57], shall be subject to requirements of this Regulation only if, from that date, those products are subject to substantial modifications ■ .
3. By way of derogation from paragraph 2, the obligations laid down in Article 11 shall apply to all products with digital elements *that fall* within the scope of this Regulation that have been placed on the market before ... [date of application of this Regulation referred to in Article 57].

Article 56
Evaluation and review

1. By ... [36 months **from** the date of application of this Regulation] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

2. ***By ... [24 months from the date of application of Article 11 as laid down in Article 57], the Commission, after consulting ENISA and the CSIRTs network, shall submit a report to the European Parliament and to the Council, assessing the effectiveness of the single reporting platform set out in Article 11b, as well as the impact of the application of the cybersecurity related grounds referred to paragraph 2 of Article 11b by the CSIRTs on the effectiveness of that platform as regards the timely dissemination of received notifications to the CSIRTs.***

Article 57
Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

2. It shall apply from ... [36 months **from** the date of entry into force of this Regulation]. However Article 11 shall apply from ... [21 months **from** the date of entry into force of this Regulation].

3. ***By way of derogation from paragraph 2, Chapter IV shall apply from ... [18 months from the date of entry into force of this Regulation];***

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at ...,

For the European Parliament

The President

For the Council

The President

Annex I

ESSENTIAL CYBERSECURITY REQUIREMENTS

Part I Security requirements relating to the properties of products with digital elements

- (1) Products with digital elements shall be designed, developed and produced in such a way that they ensure an appropriate level of cybersecurity based on the risks;

■

- (3) On the basis of the *cybersecurity* risk assessment referred to in Article 10(2) and where applicable, products with digital elements shall:

(-a) be made available on the market without known exploitable vulnerabilities;

- (a) be *made available on the market* with a secure by default configuration, *unless otherwise agreed between manufacturer and business user in relation to a tailor-made product with digital elements*, including the possibility to reset the product to its original state;

(ab) ensure that vulnerabilities can be addressed through security updates, including, where applicable, through automatic security updates that are installed within an appropriate timeframe enabled as a default setting, with a clear and easy-to-use opt-out mechanism, through the notification of available updates to users, and the option to temporarily postpone them;

- (b) ensure protection from unauthorised access by appropriate control mechanisms, including but not limited to authentication, identity or access management systems, *as well as report on possible unauthorised access;*

- (c) protect the confidentiality of stored, transmitted or otherwise processed data, personal or other, such as by encrypting relevant data at rest or in transit by state of the art mechanisms, **and by using other technical means**;
- (d) protect the integrity of stored, transmitted or otherwise processed data, personal or other, commands, programs and configuration against any manipulation or modification not authorised by the user, as well as report on corruptions;
- (e) process only data, personal or other, that are adequate, relevant and limited to what is necessary in relation to the intended **purpose** of the product ('minimisation of data');
- (f) protect the availability of essential **and basic** functions, **also after an incident**, including **with** resilience ■ and mitigation **measures against** denial-of-service attacks;
- (g) minimise **the** negative impact **by themselves or connected devices** on the availability of services provided by other devices or networks;
- (h) be designed, developed and produced to limit attack surfaces, including external interfaces;
- (i) be designed, developed and produced to reduce the impact of an incident using appropriate exploitation mitigation mechanisms and techniques;
- (j) provide security related information by recording and/or monitoring relevant internal activity, including the access to or modification of data, services or functions, **with an opt-out mechanism for the user**;

■

- (l) *provide the possibility for users to securely and easily remove on a permanent basis all data and settings and, where such data can be transferred to other products or systems, ensure this is done in a secure manner.*

Part II Vulnerability handling requirements

Manufacturers of the products with digital elements shall:

- (1) identify and document vulnerabilities and components contained in the product, including by drawing up a software bill of materials in a commonly used and machine-readable format covering at the very least the top-level dependencies of the product;
- (2) in relation to the risks posed to the products with digital elements, address and remediate vulnerabilities without delay, including by providing security updates; *where technically feasible, new security updates shall be provided separately from functionality updates;*
- (3) apply effective and regular tests and reviews of the security of the product with digital elements;
- (4) once a security update has been made available, *share and publicly* disclose information about fixed vulnerabilities, including a description of the vulnerabilities, information allowing users to identify the product with digital elements affected, the impacts of the vulnerabilities, their severity and *clear and accessible* information helping users to remediate the vulnerabilities; *in duly justified cases, where manufacturers consider the security risks of publication to outweigh the security benefits, they may delay making public information regarding a fixed vulnerability until after users have been given the possibility to apply the relevant patch;*
- (5) put in place and enforce a policy on coordinated vulnerability disclosure;

- (6) take measures to facilitate the sharing of information about potential vulnerabilities in their product with digital elements as well as in third party components contained in that product, including by providing a contact address for the reporting of the vulnerabilities discovered in the product with digital elements;
- (7) provide for mechanisms to securely distribute updates for products with digital elements to ensure that ■ vulnerabilities are fixed or mitigated in a timely *manner, and, where applicable for security updates, in an automatic* manner;
- (8) ensure that, where security ■ updates are available to address identified security issues, they are disseminated without delay and, *unless otherwise agreed between manufacturer and business user in relation to a tailor-made product with digital elements*, free of charge, accompanied by advisory messages providing users with the relevant information, including on potential action to be taken.

Annex II

INFORMATION AND INSTRUCTIONS TO THE USER

As a minimum, the product with digital elements shall be accompanied by:

1. the name, registered trade name or registered trade mark of the manufacturer, and the postal address, ■ the email address *or other digital contact as well as*, where *available the website at which the manufacturer can be contacted*;
2. the *single* point of contact where information about ■ vulnerabilities of the product *with digital elements* can be reported and received, *and where the manufacturer's policy on coordinated vulnerability disclosure can be found*;
3. *Name and type and any additional information enabling the unique* identification of the product ■ ;
4. the intended *purpose*, including the security environment provided by the manufacturer, as well as the product's essential functionalities and information about the security properties;
5. any known or foreseeable circumstance, related to the use of the product with digital elements in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to significant cybersecurity risks;
-
7. where applicable, the internet address at which the EU declaration of conformity can be accessed;
8. the type of technical security support offered by the manufacturer and *the end-date of the support period during which users can expect vulnerabilities to be handled and* to receive security updates;

9. detailed instructions or an internet address referring to such detailed instructions and information on:
- (a) the necessary measures during initial commissioning and throughout the lifetime of the product to ensure its secure use;
 - (b) how changes to the product can affect the security of data;
 - (c) how security-relevant updates can be installed;
 - (d) the secure decommissioning of the product, including information on how user data can be securely removed.
- (da) how the default setting enabling the automatic installation of security updates, as required by point (ab) of section 1.3 of Annex I, can be turned off.*
- (f) where the product with digital elements is intended for integration into other products with digital elements, the information necessary for the integrator to comply with the essential requirements in Annex I as well as documentation requirements in Annex V of this Regulation.*
10. *If the manufacturer decides to make available the software bill of materials to the user, information on where the software bill of materials can be accessed.*

Annex III

IMPORTANT PRODUCTS WITH DIGITAL ELEMENTS

■ Class I

1. Identity management systems ■ and privileged access management software *and hardware, including authentication and access control readers, including biometric readers*;
2. Standalone and embedded browsers;
3. Password managers;
4. Software that searches for, removes, or quarantines malicious software;
5. Products with digital elements with the function of virtual private network (VPN);
6. Network management systems;

■

10. Security information and event management (SIEM) systems;
11. ■ Boot managers;

■

14a. Public key infrastructure and digital certificate issuance software;

15. Physical *and virtual* network interfaces;
16. Operating systems ■ ;

■

18. Routers, modems intended for the connection to the internet, and switches ■ ;
19. Microprocessors *with security-related functionalities*;

- 20. Microcontrollers *with security-related functionalities*;
- 21. Application specific integrated circuits (ASIC) and field-programmable gate arrays (FPGA) *with security-related functionalities*;
-
- 24. *Smart home general purpose virtual assistants*;
- 25. *Smart home products with security functionalities, including smart door locks, security cameras, baby monitoring systems and alarm systems*;
- 26. *Internet connected toys covered by Directive 2009/48/EC that have social interactive features (e.g. speaking or filming) or that have location tracking features*;
- 27. *Personal wearable products to be worn or placed on a human body that have a health monitoring (such as tracking) purpose and to which Regulation (EU) 2017/745 or Regulation (EU) 2017/746 do not apply or personal wearable products that are intended for the use by and for children.*

■ Class II

-
- 2. Hypervisors and container runtime systems that support virtualised execution of operating systems and similar environments;

-
- 4. Firewalls, intrusion detection and/or prevention systems ■ ;

- 5. *Tamper-resistant* microprocessors;

- 5a. *Tamper-resistant microcontrollers*;

■

Annex IIIa

CRITICAL PRODUCTS WITH DIGITAL ELEMENTS

1. *Hardware Devices with Security Boxes;*
2. *Smart meter gateways within smart metering systems as defined in Article 2 (23) of Directive (EU) 2019/944 and other devices for advanced security purposes, including for secure cryptoprocessing.*
3. *Smartcards or similar devices, including secure elements;*

Annex IV

EU DECLARATION OF CONFORMITY

The EU declaration of conformity referred to in Article 20, shall contain all of the following information:

1. Name and type and any additional information enabling the unique identification of the product with digital elements;
2. Name and address of the manufacturer or his authorised representative;
3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider;
4. Object of the declaration (identification of the product allowing traceability. It may include a photograph, where appropriate);
5. A statement that the object of the declaration described above is in conformity with the relevant Union harmonisation legislation;
6. References to any relevant harmonised standards used or any other common specification or cybersecurity certification in relation to which conformity is declared;
7. Where applicable, the name and number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate issued;
8. Additional information:

Signed for and on behalf of:.....

(place and date of issue):

(name, function) (signature):

Annex IVa

SIMPLIFIED EU DECLARATION OF CONFORMITY

The simplified EU declaration of conformity referred to in Article [10(11)] shall be provided as follows:

Hereby, [Name of manufacturer] declares that the product with digital elements type [designation of type of product with digital element] is in compliance with Regulation XX.

The full text of the EU declaration of conformity is available at the following internet address:

Annex V

CONTENTS OF THE TECHNICAL DOCUMENTATION

The technical documentation referred to in Article 23 shall contain at least the following information, as applicable to the relevant product with digital elements:

1. a general description of the product with digital elements, including:
 - (a) its intended purpose;
 - (b) versions of software affecting compliance with essential requirements;
 - (c) where the product with digital elements is a hardware product, photographs or illustrations showing external features, marking and internal layout;
 - (d) user information and instructions as set out in Annex II;
2. a description of the design, development and production of the product and vulnerability handling processes, including:
 - (a) **necessary** information on the design and development of the product with digital elements, including, where applicable, drawings and schemes and/or a description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing;
 - (b) **necessary** information and specifications of the vulnerability handling processes put in place by the manufacturer, including the software bill of materials, the coordinated vulnerability disclosure policy, evidence of the provision of a contact address for the reporting of the vulnerabilities and a description of the technical solutions chosen for the secure distribution of updates;
 - (c) **necessary** information and specifications of the production and monitoring processes of the product with digital elements and the validation of these processes.

3. an assessment of the cybersecurity risks against which the product with digital elements is designed, developed, produced, delivered and maintained as laid down in Article 10 of this Regulation, *including how the essential requirements set out in Annex I, Section 1, are applicable*;
- 3a. *relevant information that was taken into account to determine the support period as referred to in Article 10(6) of the product with digital elements*;
4. a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, common specifications as set out in Article 19 of this Regulation or cybersecurity certification schemes under Regulation (EU) 2019/881 pursuant to Article 18(3), and, where those harmonised standards, common specifications or cybersecurity certification schemes have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Sections 1 and 2 of Annex I, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, common specifications or cybersecurity certifications, the technical documentation shall specify the parts which have been applied;
5. reports of the tests carried out to verify the conformity of the product and of the vulnerability handling processes with the applicable essential requirements as set out in Sections 1 and 2 of Annex I;
6. a copy of the EU declaration of conformity;
7. where applicable, the software bill of materials as defined in Article 3, point (36), further to a reasoned request from a market surveillance authority provided that it is necessary in order for this authority to be able to check compliance with the essential requirements set out in Annex I.

CONFORMITY ASSESSMENT PROCEDURES

Part I ■ Conformity Assessment procedure based on internal control (based on Module A)

1. Internal control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on its sole responsibility that the products with digital elements satisfy all the essential requirements set out in Section 1 of Annex I and the manufacturer meets the essential requirements set out in Section 2 of Annex I.

2. The manufacturer shall draw up the technical documentation described in Annex V.

3. Design, development, production and vulnerability handling of products with digital elements

The manufacturer shall take all measures necessary so that the design, development, production and vulnerability handling processes and their monitoring ensure compliance of the manufactured or developed products with digital elements and of the processes put in place by the manufacturer with the essential requirements set out in sections 1 and 2 of Annex I.

4. Conformity marking and declaration of conformity

4.1. The manufacturer shall affix the CE to each individual product with digital elements that satisfies the applicable requirements of this Regulation.

4.2. The manufacturer shall draw up a written EU declaration of conformity for each product with digital elements in accordance with Article 20 and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product with digital elements has been placed on the market *or the support period, whichever is longer*. The EU declaration of conformity shall identify the product with digital elements for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representatives

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Part II ■ EU-type examination (based on Module B)

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design and development of a product and the vulnerability handling processes put in place by the manufacturer, and attests that a product with digital elements meets the essential requirements set out in Section 1 of Annex I and that the manufacturer meets the essential requirements set out in Section 2 of Annex I.
2. EU-type examination shall be carried out by assessment of the adequacy of the technical design and development of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens of one or more critical parts of the product (combination of production type and design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- a written declaration that the same application has not been lodged with any other notified body;

- the technical documentation, which shall make it possible to assess the product's conformity with the applicable essential requirements as set out in Section 1 of Annex I and the manufacturer's vulnerability handling processes set out in Section 2 of Annex I, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, at least the elements set out in Annex V;
- the supporting evidence for the adequacy of the technical design and development solutions and vulnerability handling processes. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

- 4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design and development of the product with the essential requirements set out in Section 1 of Annex I and of the vulnerability handling processes put in place by the manufacturer with the essential requirements set out in Section 2 of Annex I;
- 4.2. verify that the specimen(s) have been developed or manufactured in conformity with the technical documentation, and identify the elements which have been designed and developed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed and developed without applying the relevant provisions of those standards;
- 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications for the requirements set out in Annex I, these have been applied correctly;

- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications for the requirements set out in Annex I have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements;
- 4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type and the vulnerability handling processes meet the essential requirements set out in Annex I, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type and vulnerability handling processes. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured or developed products with the examined type and vulnerability handling processes to be evaluated and to allow for in-service control.

Where the type and the vulnerability handling processes do not satisfy the applicable essential requirements set out in Annex I, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type and the vulnerability handling processes may no longer comply with the applicable essential requirements set out in Annex I to this Regulation, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type and the vulnerability handling processes that may affect the conformity with the essential requirements set out in Annex I, or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

- 7a. *The notified body shall carry out periodic audits to ensure that the vulnerability handling processes as set out in Section 2 of Annex I are implemented adequately.***

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market *or for the support period, whichever is longer.*
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Part III ■ Conformity to type based on internal production control (based on Module C)

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the essential requirements set out in Section 1 of Annex I *and that the manufacturer meets the essential requirements set out in Section 2 of Annex I.*
2. Production
 - 2.1. The manufacturer shall take all measures necessary so that the production and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the essential requirements as set out in Section 1 of Annex I *and ensures that the manufacturer meets the essential requirements set out in Section 2 of Annex I.*

3. Conformity marking and declaration of conformity

- 3.1. The manufacturer shall affix the CE marking to each individual product that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the legislative instrument.
- 3.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market *or for the support period, whichever is longer*. The declaration of conformity shall identify the product model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Part IV ■ Conformity based on full quality assurance (based on Module H)

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products (or product categories) concerned satisfy the essential requirements set out in Section 1 of Annex I, and that the vulnerability handling processes put in place by the manufacturer meet the requirements set out in Section 2 of Annex I.

2. Design, development, production and vulnerability handling of products with digital elements

The manufacturer shall operate an approved quality system as specified in point 3 for the design, development *and final product inspection and testing* of the products concerned and for handling vulnerabilities, maintain its effectiveness throughout the *time* the products concerned *are expected to be in use*, and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- the technical documentation for one model of each category of products intended to be manufactured or developed. The technical documentation shall, wherever applicable, contain at least the elements as set out in Annex V;
- the documentation concerning the quality system; and
- a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the products with the essential requirements set out in Section 1 of Annex I and compliance of the vulnerability handling processes put in place by the manufacturer with the requirements set out in Section 2 of Annex I.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design, development, product quality and vulnerability handling;

- the technical design and development specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements set out in Section 1 of Annex I that apply to the products will be met;
- the procedural specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements set out in Section 2 of Annex I that apply to the manufacturer will be met;
- the design and development control, as well as design and development verification techniques, processes and systematic actions that will be used when designing and developing the products pertaining to the product category covered;
- the corresponding production, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after production, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc;
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Regulation. The audit shall include an assessment visit to the manufacturer's premises, where such premises exist. The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, development, production, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
- the quality system documentation;
 - the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
 - the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
5. Conformity marking and declaration of conformity
- 5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the requirements set out in Section 1 of Annex I to this Regulation.
- 5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market ***or for the support period, whichever is longer***. The declaration of conformity shall identify the product model for which it has been drawn up.
- A copy of the declaration of conformity shall be made available to the relevant authorities upon request.
6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market ***or for the support period, whichever is longer***, keep at the disposal of the national authorities:
- the technical documentation referred to in point 3.1;

- the documentation concerning the quality system referred to in point 3.1;
- the change referred to in point 3.5, as approved;
- the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Joint political statement by the European Parliament, the Council and the European Commission on ENISA resources on the occasion of the adoption of Regulation (EU) .../...of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements, amending Regulations (EU) 168/2013 and (EU) 2019/1020 and Directive 2020/1828/EC (Cyber Resilience Act)*

The European Parliament and the Council consider that this Regulation confers additional tasks on ENISA which result in additional workload and would require additional resources in terms of both expertise and number. In view of this, in order to enable ENISA to effectively carry out the tasks under this Regulation, the European Parliament, the Council and the European Commission consider that an increase in its resources, in particular its human resources with the adequate expertise, may be necessary. Such increase could be provided for in the annual procedure related to the establishment plan of ENISA. Accordingly, the Commission, which is responsible for entering in the draft general budget of the Union the estimates it deems to be necessary for ENISA's establishment plan, in the framework of the budgetary procedure set out in Article 314 TFEU and in accordance the procedure set out in the Cybersecurity Act, shall assess the estimates for the establishment plan of ENISA entered for the first year after entry into force of this Regulation in consideration of the necessary resources, in particular human resources, to enable ENISA to adequately carry out its tasks under this Regulation.

** [The provisional political agreement concluded to have this statement published in the C-Series of the Official Journal and to have a reference and a link to them in the L-Series, together with the legislative act.]*