BRIEFING
EU Legislation in Progress

European Parliament

EU cyber-resilience act

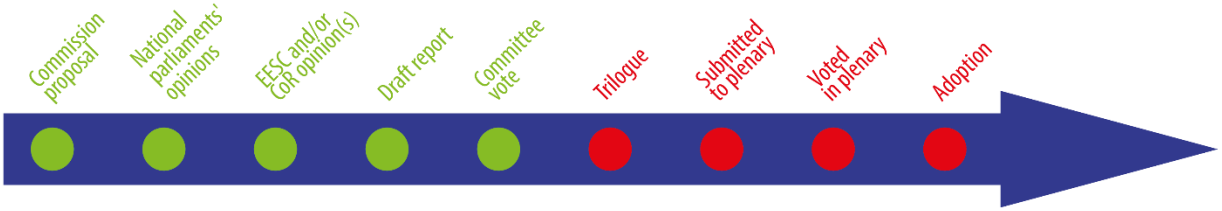
OVERVIEW

New technologies come with new risks, and the impact of cyber-attacks through digital products has increased dramatically in recent years. Consumers are increasingly falling victim to security flaws linked to digital products such as baby monitors, robo-vacuum cleaners, Wi-Fi routers and alarm systems. For businesses, the importance of ensuring that digital products in the supply chain are secure has become pivotal, considering three in five vendors have already lost money owing to product security gaps.

The European Commission's proposal for a regulation, the 'cyber-resilience act', therefore aims to impose cybersecurity obligations on all products with digital elements whose intended and foreseeable use includes direct or indirect data connection to a device or network. The proposal introduces cybersecurity by design and by default principles and imposes a duty of care for the lifecycle of products.

The Council and the Parliament are currently in negotiations to finalise the text.

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		
Committee responsible:	Industry, Research and Energy (ITRE)	COM(2022)454 15.9.2022
Rapporteur:	Nicola Danti (Renew, Italy)	2022/0272(COD)
Shadow rapporteurs:	Henna Virkkunen (EPP, Finland) Beatrice Covassi (S&D, Italy) Ignazio Corrao (Greens/EFA, Italy) Evžen Tošenovský (ECR, Czechia) Matteo Gazzini (ID, Italy) Marc Botenga (The Left, Belgium)	Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
Next steps expected:	Continuing trilogue negotiations	



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Introduction

According to an industry forecast, the total number of internet of things (IoT) connected devices worldwide is set to more than double from 13.2 billion in 2022 to 34.7 billion by 2028. Another report estimates that the number of devices connected to Internet Protocol (IP) networks will be more than three times the global population by 2023.

Cybersecurity flaws in connected products come with a cost. In its 2020 report Cybersecurity – Our Digital Anchor, the Commission highlighted how ransomware attacks hit organisations every 11 seconds around the globe. It is expected that by 2031 there will be a new attack on a consumer or business every 2 seconds, costing victims around US$265 billion (€251 billion) annually. The European Union Agency for Cybersecurity's (ENISA) 2022 report on the threat landscape in the EU revealed that 10 terabytes of data are stolen every month. The 2023 edition of the report confirmed the trend that ransomware is the most frequent form of cyberattacks in the EU, followed closely by distributed denial of service attacks (DDoS),[1] with DDOS becoming increasingly larger, complex and inexpensive, and increasingly targeting mobile networks and IoT.[2] In addition, the ENISA foresight report identified 'supply chain compromise of software dependencies' as the number one cybersecurity threat likely to emerge by 2030.

Given the growth in smart and connected products, a cybersecurity incident in one product can affect the entire supply chain, potentially disrupting social and economic activities across the internal market. An example is the Kaseya VSA supply chain attack of July 2021. This ransomware attacked over 1 000 companies and forced a supermarket chain to close all of its 500 shops across Sweden. Cisco reports that just 9 % of companies in Europe have a sufficiently mature level of readiness to be resilient against modern cyber threats.

In addition, European consumers' increasing use of connected devices (e.g. smart-home appliances) and the related risks should not be underestimated. According to a 2021 Eurobarometer survey, 56 % of citizens believe that they are facing an increasing risk of falling victim to cybercrime, such as theft or abuse of personal data, malicious software or phishing. It is therefore not surprising that the EU citizens who took part in the Commission's 2023 digital decade survey ranked the protection of users from cyber-attacks as a top priority. Even toys have the potential to pose such risks. In February 2017, the German regulator banned a connected doll Cayla, deemed insecure both from a privacy point of view and as a potential concealed surveillance device. The doll could potentially allow anyone in close proximity to listen to and record conversations between the child and the toy by hacking the Bluetooth device connection.

Existing situation

In her 2021 State of the Union address, European Commission President Ursula von der Leyen announced the cyber-resilience act proposal (CRA), stating that 'If everything is connected, everything can be hacked. Given that resources are scarce, we have to bundle our forces [...] This is why we need a European cyber defence policy, including legislation setting common standards under a new European cyber-resilience act'.

Cybersecurity is one of the Commission's top priorities for a digital and connected Europe, and the CRA, once adopted, would be one of the building blocks of the Commission's EU cybersecurity strategy for the digital decade. It is also in line with the EU's priorities to create a Europe fit for the digital age in which digital transformation will benefit both people and businesses. The cybersecurity strategy acknowledges that improving cybersecurity is essential for people to trust, use and benefit from innovation, connectivity and automation, and for safeguarding fundamental rights and freedoms, including the right to protection of personal data and the freedom of expression. The existing EU cybersecurity framework comprises several pieces of legislation that cover specific aspects of cybersecurity from different angles.

The Directive on Attacks against Information Systems, which focuses on criminal law, came into force in 2013 and harmonised criminalisation and penalties for a number of offences directed against information systems. A linked piece of legislation, the Directive on Security of Network and Information Systems across the EU (the NIS Directive) came into force in 2016, and introduced horizontal legal measures to boost the overall level of cybersecurity in the EU with a focus on protecting critical infrastructure. In December 2022, it was replaced by the Directive on the Security of Network and Information Systems (NIS2 Directive), which removed its predecessor's limitations and is to be transposed into national law by 17 October 2024. In addition, sectoral legislation, such as the Directive on the Resilience of Critical Entities (CER) and the Regulation on Operational Resilience of the Financial Sector (DORA) set specific security and reporting requirements in their areas. As far as information and communication technology (ICT) products, services and processes are concerned, in 2019 the EU Cybersecurity Act strengthened the powers of ENISA and introduced a **voluntary certification scheme** to apply to the cybersecurity features of an ICT product, service or process. Although the scheme remains voluntary for businesses, it may be used for compliance with the mandatory safety requirements of other legal acts.

In addition, the EU has adopted specific sectoral legislation on safety for products with digital elements: the Radio Equipment Directive (RED), the Medical Device Regulation, the In Vitro Diagnostic Medical Devices Regulation, the Vehicle General Safety Regulation, the Common Rules in Civil Aviation Regulation and the Machinery Regulation. Lastly, the proposed artificial intelligence act mandates an ex-ante conformity assessment for high-risk artificial intelligence (AI) systems.[3] At present, there are no general cybersecurity requirements at EU level for any hardware and software that is not specific to certain products or sectors, as confirmed by Internal Market Commissioner Thierry Breton, who said that 'most of the hardware and software products are currently not covered by any legislation regarding their cybersecurity'. A 2019 opinion produced by the ENISA advisory group confirms this statement, reporting that 'connected devices for consumers often do not include the most basic security features, and are therefore vulnerable to the most basic cyberattacks and misuse'. For instance, the delegated regulation supplementing the RED Directive deals with the security of consumer IoT devices by imposing a high level of requirements on manufacturers of internet-connected wireless and wearable radio equipment, asking them to incorporate safeguards to ensure personal data protection. However, because of a 30-month transition period, the RED requirements will be applicable only from August 2024. Once the proposed CRA becomes applicable, the RED delegated regulation will be repealed. In addition, the EU legal framework does not address the cybersecurity of non-embedded software represented by applications such as navigation software or in-car entertainment systems. Moreover, how economic operators address the vulnerabilities of products with digital elements throughout their lifecycle is an issue that demands further attention.

Member States have already adopted or proposed cybersecurity requirements for consumer IoT.[4] However, the absence of a cybersecurity legal framework for products with digital elements incentivises the development of potentially diverging national rules among Member States, threatening the openness and competitiveness of the single market.

Parliament's starting position

In its resolution of 3 October 2017 on the fight against cybercrime, Parliament stressed that particular attention should be paid to the security of IoT devices, calling for a security-by-design approach to be taken to all such devices. In its 10 June 2021 resolution on the EU's cybersecurity strategy for the digital decade, Parliament called for security-by-design and cyber resilience for all internet connected products along the entire supply chain. Parliament welcomed the 'Commission's plans to propose horizontal legislation on cybersecurity requirements for connected products and associated services', with a view to harmonising national laws and hence preventing fragmentation of the single market. In addition, it asked the Commission to shape a horizontal regulation on cybersecurity requirements for apps, software (including embedded software), and operating systems by 2023. This regulation should require manufacturers to include information for users on the duration of security updates.

Council starting position

In its conclusions of 2 December 2020, the Council acknowledged the increased cybersecurity risks for connected devices. It expressed the need to minimise cybersecurity risks in order to protect consumers and to increase Europe's cyber-resilience to foster competitiveness and innovation. In its conclusions of 23 May 2022, the Council called on the Commission to propose, through the CRA, common EU cybersecurity requirements for connected devices and associated processes and services by the end of 2022. According to the Council, the proposal should take into account 'the need for a horizontal and holistic approach that covers the whole lifecycle of digital products, as well as existing regulation, especially in the area of cybersecurity'.

Preparation of the proposal

The European Commission outsourced a study to support the preparation of the impact assessment (IA) published together with the proposal. In addition, to collect stakeholders' opinions, the Commission held an open public consultation that closed in May 2022, and organised workshops, surveys and expert interviews. Special efforts were also made to gather SMEs' views on the impacts of the possible policy options. EPRS published an initial appraisal of the Commission impact assessment of the proposed cyber-resilience act in December 2022.

The changes the proposal would bring

As the first ever EU-wide legislation of its kind, the proposed EU cyber-resilience act seeks to bolster the cybersecurity of products with digital elements (digital products) in the European Union and to address existing regulatory cybersecurity gaps. Devices with digital elements that fail to meet the requirements of the CRA would be banned from the EU market. As the CRA would also target digital products from non-EU vendors when marketed in the EU, it might have a potential impact on the cybersecurity standards for such products beyond EU borders. The EU would serve as the international point of reference on cybersecurity of connected devices the same way that the General Data Protection Regulation does for privacy. Indeed, rather than create different products or processes for different markets, non-EU companies might find it more convenient to apply the proposed mandatory CRA rules – and thereby secure an access to the EU single market for their digital products – as a default framework for their global operations.

Principle and objectives

The proposed CRA is a **piece of horizontal legislation** based on Article 114 of the Treaty on the Functioning of the EU (ordinary legislative procedure applies) dealing with legislative harmonisation and the establishment and functioning of the internal market. It aims to harmonise cybersecurity rules for the placing on the market of products with digital elements. EU standards based on the CRA would raise the level of cybersecurity for digital products, benefiting both businesses and consumers.

The proposed CRA has two main objectives for digital products (i.e. hardware and software), and its aim is to create the conditions for the development of secure digital products, by ensuring that hardware and software products are placed on the market with fewer vulnerabilities. It also aims to oblige manufacturers to take security seriously throughout products' lifecycles, and to encourage users to take cybersecurity into account when selecting and using products.

Scope

In Article 3(1), the CRA defines **products with digital elements** as 'any software or hardware product and its remote data processing solutions, including software or hardware components to be placed on the market separately'. In Article 2(1), it further clarifies that the proposed regulation applies to 'products with digital elements whose intended or reasonably foreseeable use includes a direct or indirect logical or physical data connection to a device or network'. Therefore, the proposed CRA is a horizontal regulation that, with a few exceptions, covers a very wide range of digital products, such as connected devices (e.g. consumer and industrial IoT), operating systems and non-

embedded software. The proposal also covers AI systems, including the cybersecurity of products with digital elements that are classified as high-risk AI systems.

Excluded from the proposal's coverage are digital devices covered by specific sectoral regulations[5] and software-as-a-service (SaaS), such as clouds, unless they are part of integral remote data processing solutions for a product with digital elements. Last but not least, in order not to hamper innovation or research, free not-for-profit open source software is not covered by the proposal.

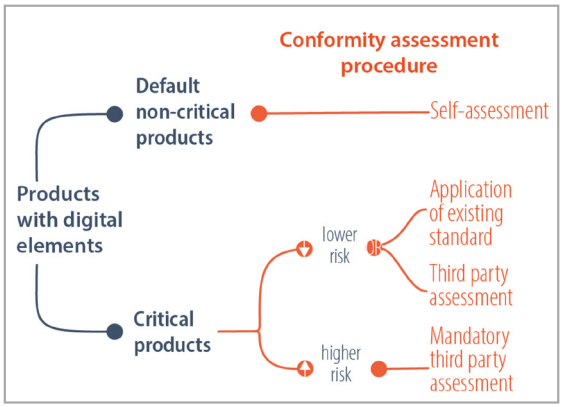
The proposed CRA divides the digital products it covers into two main categories, based on their level of risk. The first is **default non-critical products**, i.e. hardware and software with a low level of criticality (e.g. hard drives, smart home assistants or connected toys). The second is **critical products** (listed under Annex III), which are further divided into two sub-categories, class I lower risk (e.g. virtual private networks and routers) and class II higher risk (e.g. operating systems for desktops and mobile phones or smart meters) reflecting criticality and intended use.

Based on their level of risk, the above-mentioned digital products would be subject to less or more stringent conformity assessment procedures to demonstrate compliance with the cybersecurity obligations set in the proposed regulation. Such procedures range from a simple cybersecurity self-assessment to a third-party conformity assessment.

For **non-critical products**, which represent 90 % of digital products placed on the market, manufacturers would have to declare under their own responsibility that the devices with digital elements comply with all the security requirements defined in the draft CRA (self-assessment).

For **critical products**, the process to demonstrate compliance differs, based on the sub-category taken into consideration. For **critical class I** products (lower risks), the manufacturer may still carry out a self-assessment under their own responsibility as long as they apply to their product existing i) harmonised cybersecurity standards (e.g. developed by European standardisation organisations); or ii) cybersecurity certification schemes under the EU Cybersecurity Act. In the absence of such standards and schemes for the product in question, or if the manufacturer has not applied or has only applied in part the standards or schemes, the manufacturer would have to undertake a conformity assessment performed by a third party (conformity assessment body, CAB). For **critical class II** products, manufacturers would be subject to the third party conformity assessment run by a CAB.

Figure 1 – Cyber-resilience conformity assessment



Source: European Commission.

The proposed CRA places cybersecurity obligations on different economic operators in accordance with their roles and responsibilities in the supply chain. **Manufacturers** would need to ensure that digital products comply with essential cybersecurity requirements and conformity assessment procedures before placing them on the market. In addition, they would need to record technical documentation and abide by notification obligations for cybersecurity breaches. **Importers** would have to place on the market only digital products that comply with essential cybersecurity requirements and bear the CE marking. **Distributors** would have to verify that the digital products bear the CE marking. They would also have a duty of care to ensure that manufacturers and importers have complied with their obligations under the act.

Main provisions

Cybersecurity by design and by default

Manufacturers would be required to consider cybersecurity starting from the design and development phase of the digital product, by using secure-by-default configurations and avoiding

known exploitable vulnerabilities. The annexes of the proposed CRA include: i) the information manufacturers should make available to users; ii) conformity assessment procedures digital products would have to go through; and iii) the technical documentation that needs to be provided. In addition, Annex I (2) details the vulnerability handling requirements manufacturers would have to follow to assure the cybersecurity of digital products.

Essential cybersecurity and vulnerability handling requirements, including reporting obligations

The proposed CRA splits the cybersecurity obligations for manufacturers into i) security requirements relating to the properties of digital products; and ii) vulnerability handling requirements.

Significant **cybersecurity requirements** listed in Annex I include obligations to: i) design, develop and produce digital products in such a way that limits their attack surface and reduces the impact of any incident based on the risks; ii) deliver digital products without known exploitable vulnerabilities; iii) protect the confidentiality and integrity of data stored, transmitted or processed; iv) process only data, personal or other, that are strictly necessary to the functioning of the digital product – 'data minimisation'.

As regards **vulnerability handling**, after the product has been placed on the market, manufacturers would have to deploy, among other things, regular tests and reviews of their digital products' security, keep a record of vulnerabilities identified, and remediate them by providing free security updates and patches. The manufacturers will be required to do so for the expected product lifetime or for a period of 5 years, whichever is shorter.

Finally, manufacturers will have to report actively exploited vulnerabilities and security incidents to ENISA within 24 hours of becoming aware of them.

Conformity assessment and compliance

The type of conformity assessment procedure applied to demonstrate compliance with the requirements mentioned above depends on the criticality of the digital product (see Figure 1). The digital products demonstrating compliance with the security requirements and the conformity assessment procedures will obtain an EU declaration of conformity valid in all EU Member States and will bear the CE marking according to the general principles of Regulation (EC) 765/2008.

Fines

Member States will appoint market surveillance authorities, which will be responsible for the enforcement of the proposed CRA obligations. In case of non-compliance with the obligations set out in the proposal, the following maximum fines would apply depending on the type of infringement and nature of the economic operator. **Manufacturers**, for instance, could risk a fine of €15 million or 2.5 % of their total annual turnover worldwide, whichever is higher, for non-compliance with the security requirements listed under Annex I. **Manufacturers**, **importers**, or **distributors** could risk a fine of €10 million or 2 % of their total annual turnover worldwide, whichever is higher, for non-compliance with any other obligation laid down in the draft regulation.

Interplay between the conformity assessment procedure and existing or upcoming cybersecurity legislation

The proposed CRA and the conformity assessment procedure it lays out dovetail with other pieces of existing or proposed legislation on cybersecurity. The proposal aims to harmonise the EU regulatory landscape by introducing cybersecurity requirements for products with digital elements without overlapping with requirements stemming from the pieces of legislation listed below.

Starting with **existing legislation**, the CRA proposal would complement the baseline EU cybersecurity framework, namely the NIS2 Directive and the EU Cybersecurity Act. The NIS2 Directive puts in place cybersecurity requirements and incident reporting obligations for essential and important entities with a view to increasing their resilience – for example, a clear obligation to demonstrate how those entities have assessed the security level of the ICT products and services.

Therefore, the enhanced and certified level of cybersecurity of products with digital elements – to be reached through the CRA – would facilitate compliance by the entities within the scope of the NIS2 Directive and strengthen the security of the entire supply chain.

The EU Cybersecurity Act provides for the development of voluntary certification schemes. Each scheme includes references to relevant standards, technical specifications and other cybersecurity requirements defined in the scheme. Digital products respecting such voluntary cybersecurity certification schemes would be presumed to be compliant with the conformity assessment provided for in the proposed CRA. Finally, the proposed CRA applies to radio equipment within the scope of the RED delegated regulation. The proposal is aligned with those requirements of the RED delegated regulation that impose high-level standards on manufacturers of internet-connected wireless and wearable radio equipment. To avoid a regulatory overlap, the Commission would repeal the RED delegated regulation with respect to specific radio equipment that is also covered by the proposed CRA once it enters into force.

Digital products covered in the Machinery Regulation, and for which a conformity assessment is required, would be considered to be in conformity with the proposed CRA, providing the health and safety requirements of the sectoral Machinery Regulation are met.

As regards **legislative proposals** under adoption, the conformity assessment procedure under the proposed CRA would also take into consideration the provisions of the artificial intelligence act proposal. As a general rule, for devices also classified as high-risk AI systems, the conformity assessment procedure under the proposed CRA would serve to demonstrate compliance with the security requirements under the artificial intelligence act. However, exceptions apply to certain AI critical products.

Advisory committees

The European Economic and Social Committee (EESC) points out potential difficulties with regard to the monitoring and oversight of the implementation of the CRA, since the proposal covers virtually all digital products. The EESC underlines the need to clarify the material scope of the CRA and take care of the particular needs of SMEs when setting criteria for services provided by the certification authorities. In addition, the EESC points out that ENISA should be given sufficient resources in view of its increased responsibilities. The EESC adopted its opinion during its plenary session of 14-15 December 2022.

National parliaments

The subsidiarity deadline for national parliament was 19 December 2022. Only the Czech Chamber of Deputies has issued a reasoned opinion.

Stakeholder views[6]

Scope of the proposal: What kind of software?

According to DigitalEurope, representing the digital technology industry in Europe, the inclusion of all software within the scope of the proposal would be an excessive and premature step, as cyber-resources are scarce both for the industry and for governments. On the other hand, Eurosmart, representing the European digital security industry, supports the inclusion of software as a product under the relative liability rules, as this would help to acknowledge the cybersecurity value chain when products relying on software are placed on the market. Internet Society, a non-governmental organisation (NGO) promoting internet development, pleads for clear exclusion of not-for-profit open-source licence software from the scope of the CRA, because of the unclear definition of commercial activity in the proposal. Business Europe, representing enterprises of all sizes, also deems it necessary to have additional clarification regarding the exclusion of open-source software that is not used in the course of a commercial activity. Industry coalitions repeatedly urged the co-legislators to exclude not-for-profit open-source software from the scope of the CRA.

Personal data as essential cybersecurity requirements

The European Data Protection Supervisor (EDPS) recommends considering personal data protection to be an 'essential cybersecurity requirement' for products with digital elements. This should be done by applying the principle of data protection by design and by default. The proposal should clarify that it does not aim to affect the powers of data protection authorities.

Classification of products based on risk

APPLiA, representing the European home appliance industry, advocates making a clear distinction between low and high-risk products and defining clear standards for each of the two categories. The European Digital SME Alliance calls for a risk-based approach, where different product categories would follow different procedures (e.g. imposing minimum requirements and compliance checks for low-risk products). Euroconsumers, association of consumer organisations, believes that the omission of consumer IoT products (e.g. connected devices intended for children) from the category of critical products should be reconsidered. Such products could be potentially harmful if hacked, and a third-party risk assessment could play a role in detecting vulnerabilities in them. BEUC, the European Consumer Organisation, confirmed this position and stated that the CRA should introduce a European cybersecurity certification scheme for all critical products as an alternative to proving their conformity. TIC Council, representing the testing, inspection and certification industry, is similarly concerned about the nature of consumer IoT products that currently fall within the low-risk category despite having the ability to collect, store and share data. Developers Alliance stresses that the Commission retains a large margin of discretion for updating the list of critical products under Annex III. Eurosmart urges for precise category definitions for products included in Annex III. Similarly, an industry coalition advocates for a proportionate approach to determining product risk levels in order to avoid unjust designation of too many products as critical.

VDMA, representing the mechanical and plant engineering industry, is concerned that classifying all core components for networked machines and systems as critical products could lead to red tape for manufacturers. According to them, many industrial components are only used for non-critical purposes. They fear that this approach could cause delays in the deployment of digital products and their components in Europe, and propose making a reference to the intended use of the products. The CEOs of six European techs companies and Digital Europe warn that a wide scope of CRA could create COVID-19 style disruptions in the EU supply chains because of bottlenecks created by obliging manufacturers to certify their products through third-party certifiers. Therefore the number of higher risk products in Annex III should be minimal. Similarly, an industry coalition believes that most products from Annex III should be placed into the non-critical category and should consequently adhere to self-assessment, to avoid excessive costs for launching new products.

Conformity assessment procedure

BEUC argues in favour of independent third-party conformity assessments also for certain products representing higher risks to consumers (e.g. safe home systems). In a similar vein, the TIC Council favours conformity assessment by bodies that are independent from the product developer. They are afraid that, as 90 % of the digital products subject to the proposed CRA will still be assessed by their manufacturers, this would leave on the market a certain amount of products that can pose risks to consumers' safety and security. Furthermore, the TIC Council demands that the TIC industry be fully recognised as a trusted partner in cybersecurity conformity assessments. TÜV Verband, association of technical inspection agencies, believes that the CRA should 'not only define cybersecurity requirements, but it must also stipulate effective instruments with which compliance with these requirements can be reliably verified'. The association considers that all critical products should undergo a compulsory assessment by independent assessment bodies. In contrast, the CCIA, computer and communications industry association, considers the conformity assessment procedures for digital products to be excessive, with the potential to stop the development of new technologies and services.

Concerns were expressed over the absence of horizontal cybersecurity standardisation schemes. For example, VDMA worries that the absence of appropriate standards could cause delays in the delivery of approved products. Eurosmart encourages different standardisation initiatives to support certification schemes for different product types as described by the CRA. They believe that the cybersecurity of critical products with digital elements should be assessed under the EU Cybersecurity Act's certification scheme at its 'high' level. Applying this scheme to critical products with digital elements would provide a presumption of conformity with the CRA requirements, because it contains mandatory penetration testing – the only way to seriously assess the robustness of such products. They also recommend making use of all available European standards rather than using only 'harmonised standards', which would have a limiting effect.

Duty of care and product lifecycle

Euroconsumers has reservations about the definition of the expected product lifetime, where the duty of care (the duty on manufacturers to monitor and address any vulnerabilities for the 'expected product lifetime') is set at a maximum of 5 years. This could be problematic, for example, for users of smart home security systems that are expected to last much longer than 5 years. Along these lines, BEUC asks for including a requirement that manufacturers provide software updates for the whole lifecycle of a product and differentiate between functionality and security updates. Contrary to this, the European Digital SME Alliance welcomes the time limit for of the duty to provide updates. An industry coalition rejects the differentiation between security and functionality updates as 'not feasible'. They believe that linking expected product lifetime solely to reasonable user expectations creates legal uncertainty. Eurosmart advocates that manufacturers should be free to define a product's expected lifetime based on its technical capacities, but they should clearly indicate it in a declaration of conformity.

Notification fatigue, reporting of unpatched vulnerabilities and transitional period

Blackberry draws attention to the burden on companies to report cybersecurity incidents to different authorities. BEUC believes that ENISA should be the central reporting entity to which any incident needs to be reported. The American Chamber of Commerce to the European Union (AmChamEU) suggests aligning the CRA's obligations on notifications with existing or draft legislation covering cyber incidents (e.g. the NIS2 Directive). Similarly, a group of CEOs supports the idea to extend the approach of the NIS2 Directive, where only significant risks are reported and the 'one incident-one report' principle applies. Eurosmart welcomes the proposal for manufacturers to report only significant incidents, which however should be clearly defined.

European Digital Rights (EDRi), an association of digital civil and human rights organisations, calls for the inclusion of safeguards in addressing the vulnerability disclosure requirements to avoid the misuse of information related to vulnerabilities. Similarly, a coalition of national, European and international associations urges for the removal of the obligation on the reporting of unpatched vulnerabilities and for limiting it only to disclosure of vulnerabilities where mitigation actions are available. This echoes the position of the digital industry coalition. It was furthermore reiterated in an open letter drafted by 57 cybersecurity experts, and in the position of another industry coalition. If actively exploited vulnerabilities remain in the scope of the regulation, a group of CEOs asks for the manufacturers to decide, at their discretion, between patching the vulnerability or immediately reporting it.

Orgalim, representing Europe's technology industries, asks that a transition period of 48 months after the entry into force of the CRA be given to ensure that the industry is prepared to comply with the new provisions. Various industry coalitions have demanded similar transition periods, ranging from 48 to 72 months. The TIC Council, on the other hand, rejects the postponement of the implementation deadline.

Academic views

Need for horizontal regulation

Ludvigsen and Nagaraja[7] recommend applying the proposed regulation to the entire supply chain and support the full transparency concept. This means that understanding the cryptography and cybersecurity tools of the product would not qualify as a trade secret for the purposes of non-disclosure of information (except for certain exemptions such as hardware verification mechanisms). Similarly, Chiara[8] advocates harmonised EU cybersecurity rules, as this would be the most efficient way to increase cyber resilience by enhancing the trust of users and the prominence of products with the CE marking. According to the author, the CRA contributes to the evolution of the concept of cybersecurity and goes beyond technical IT security. A horizontal approach would help to ensure legal certainty by avoiding further overlapping of legislation and market fragmentation. In addition, Chiara believes[9] that such an approach underpins the cybersecurity principle enshrined in the European Declaration on Digital Rights and Principles and would be fit to enforce it. Burri and Zielhmann[10] warn that the overarching goal of the CRA to be the global cybersecurity standard-setter could have the adverse effect – that of causing the fragmentation of the global data governance. The Center for Data Innovation, meanwhile, states that the horizontal framework under the CRA could entail high compliance costs and might not be sufficiently future-proof. Therefore, they recommend a sectoral approach to cybersecurity regulations, which would also minimise costs.

Risk-based approach and continuous risk assessment

According to the Center for Data Innovation's above article, the CRA should include a requirement for continuous security risk management, where digital products should be kept secure throughout their lifecycles, with penetration testing being part of this maintenance system. The authors advocate that it should be the Member States' dedicated authorities and not private organisations that should be assessing the security of digital products. Burri and Zielhmann[11] question the appropriate level of cybersecurity and protection, given that 90 % of digital products will undergo self-assessment by manufacturers. They question as well the decision to exclude from the set of considerations the environment in which a certain product will be placed, as threats and risks depend greatly on it. In addition, setting the expected lifetime of products to 5 years might create flaws, considering that many products have a longer lifetime or have already been on the market for some time, possibly beyond the expiration of the 5 year deadline.

Surveillance and enforcement

Ludvigsen and Nagaraja[12] also made several interesting proposals regarding surveillance and enforcement. Their article outlines two possible approaches for the CRA: creation of common rules at EU level and their enforcement at national level; or harmonising some measures at EU level through a central authority, such as ENISA, and entrusting the remaining ones to the national authorities. Both approaches will need to take into account the voluntary certification schemes that have been provided for by the Cybersecurity Act, but are still under development. Finally, the authors recommend adopting stringent enforcement mechanisms by giving national authorities inspection powers. As far as staff and sanctions are concerned, they suggested staffing requirements similar to those in the AI act proposal and sanctions similar to those envisaged in the GDPR, with the additional possibility of banning cyber insecure products from the market.

Burri and Zielhmann[13] find that the criteria for marker surveillance authorities to intervene in specific cases are too broad and too vague. In addition, they highlight the potential coordination problems among different national authorities because of complexity of monitoring and oversight. They warn against the risk of fragmentation of surveillance and consequently imbalance between national market surveillance authorities inside the EU because of unclear wording of the proposal, which gives the market surveillance authorities the discretion to investigate products or not to do so. More attention should also be paid to the relationship between the imposition of fines and the banning of products from the EU market, which is not yet clear enough.

Legislative process

In the Parliament, the file has been assigned to the Committee on Industry, Research and Energy (ITRE), with Nicola Danti (Renew, Italy) as rapporteur. The Committee on Internal Market and Consumer Protection (IMCO) has exclusive competence on Articles 7 and 9 and shared competence on Articles 4, 8, 21, 22 and 25-40 of the proposal. The Committee on Civil Liberties, Justice and Home Affairs (LIBE) has shared competence on Article 41(5) of the proposal. Both the IMCO and LIBE committees have been asked to submit opinions. IMCO published its opinion on 30 June 2023.

The ITRE committee adopted its report with 61 votes to 1 and 10 abstentions on 19 July 2023. The main points of the committee amendments to the Commission proposal include:

- **Scope**: The report confirms the Commission's proposal to include all products with digital elements. It underlines however the need to ensure that developers of open-source software are excluded from the scope if they are not receiving any financial returns for their projects. The report expands the list of critical products under class I, to also include home automation systems and products that enhance private security, such as cameras and smart locks.
- **Expected product lifetime**: The report gives manufacturers flexibility to determine the length of the period over which they would ensure that vulnerabilities are handled; greater clarity is needed in this regard. Manufacturers would be obliged to provide automatic security updates, with an easy-to-use option for deactivation for the users. Where feasible, they would also need to differentiate between security and functionality updates. When the support period is shorter than 5 years, the manufacturers would need to make their source code available to companies that want to provide security updates.
- **Reporting** would need to align with the NIS2 Directive in order to simplify the obligations for manufacturers, and make mandatory only reporting of significant incidents and actively exploited vulnerabilities, done through a multi-step approach (24 hours, 72 hours, 1 month). ENISA would become the one-stop entity for reporting. It should receive reinforcement to be able to fulfil its additional tasks under the regulation.
- **Application deadline**: The report proposes to prolong the moment from which the regulation applies to 36 months. In this respect, micro, small and medium-sized enterprises need to receive sufficient support to ensure their compliance. Harmonised standards and common specifications or European cybersecurity certification schemes need to be in place 6 months before the conformity assessment procedure starts applying. The Commission would need to provide guidelines with more details on the implementation.
- **Cybersecurity workforce**. The report underlines the importance of cybersecurity professionals and proposes up-skilling and re-skilling to ensure their availability.
- **Mutual recognition agreements (MRAs)** with third countries are proposed to promote international trade and ensure the same level of protection as that provided by the CRA. As regards the monitoring of non-technical risk factors, ENISA and market surveillance authorities would need to perform the necessary checks on vendors that might present a higher risk.

In the Council, Coreper reached a position on 19 July 2023, allowing the Council to enter into negotiations with the Parliament. Council notably removed the notion of 'critical' from products with digital elements and deleted a substantial number of the products listed in Annex III. Council introduced three categories of products – hardware devices with security boxes, smart meters and smart cards, grouped in a new Annex IIIa. These products, which are critical for the essential entities as defined by the NIS2 Directive, would fall under mandatory European cybersecurity certification schemes. The products' lifetime would be determined by the manufacturers, who would need to specify the year and month until when they will handle vulnerabilities. The Council moved the reporting of cybersecurity incidents and actively exploitable vulnerabilities from ENISA to the national Computer Security Incident Response Teams (CSIRTs) in a two-step process of an initial notification after 24 hours and a second one after 72 hours. Council proposed to postpone the application of the regulation to 36 months as also envisaged by the Parliament.

Parliament confirmed the decision of the ITRE committee to enter into interinstitutional negotiations on 13 September 2023. The co-legislators started trilogue negotiations on the file on 27 September. A second trilogue meeting was held on 8 November 2023.

EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

The NIS2: A high common level of cybersecurity in the EU, EPRS, European Parliament, February 2023.

ENISA and a new cybersecurity act, EPRS, European Parliament, 2019.

Strengthening cyber resilience, EPRS, European Parliament, December 2022.

OTHER SOURCES

Horizontal cybersecurity requirements for products with digital elements (Cyber Resilience Act), Legislative Observatory (OEIL), European Parliament.

Cybersecurity, our digital anchor, Joint Research Centre, European Commission, 2020.

ENDNOTES

1 The Cisco report estimates that DDoS attacks will double from 7.9 million in 2018 to 15.4 million by 2023.

2 Internet of Things (IoT) devices and networks are increasingly suffering from DDoS attacks as their resources are often limited, which causes poor security features. Weak passwords, for example, make devices easy to corrupt.

3 According to Recital (27) of the draft AIA, 'AI systems identified as high-risk should be limited to those that have a significant harmful impact on the health, safety and fundamental rights of persons in the Union and such limitation minimises any potential restriction to international trade, if any'.

4 For example, Finland and Germany apply certain security measures on a voluntary basis. Non-EU countries are also busy addressing this issue; for example, Brazil, China and Japan have adopted mandatory certification schemes for certain digital products. In the UK, a law has introduced mandatory security requirements and required a statement of compliance before a consumer IoT product can be placed on the market. In the US, an Executive Order on Improving the Nation's Cybersecurity has been published, identifying software bills of materials (SBOMs) as a crucial tool to improve the security and integrity of the software supply chain (see Congressional Research Service report).

5 Regulations on medical devices, in-vitro diagnostic medical devices, civil aviation safety, on-type approval requirements for motor vehicles and their trailers and systems. Furthermore, components and products developed exclusively for national security or military purposes and products specifically designed to process classified information are also excluded from the scope of the proposed CRA.

6 This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'European Parliament supporting analysis'.

7 See K. Ludvigsen and S. Nagaraja, The Opportunity to Regulate Cybersecurity in the EU (and the World): Recommendations for the Cybersecurity Resilience Act, Cornell University, May 2022.

8 See P. Chiara, The Cyber Resilience Act: the EU Commission's proposal for a horizontal regulation on cybersecurity for products with digital elements, International Cybersecurity Law Review, November 2022.

9 See P. Chiara, Towards a Right to Cybersecurity in EU Law? The Challenges Ahead, August, 2023.

10 See M. Burri and Z. Zihlmann, 'The EU Cyber Resilience Act – An Appraisal and Contextualization', *Zeitschrift für Europarecht* (EuZ), 2/2023, B1-B45, February 2023.

11 ibid.

12 ibid 7.

13 ibid 10.

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