



Council of the  
European Union

Brussels, 27 January 2023  
(OR. en)

5806/23

LIMITE

CYBER 14  
JAI 87  
DATAPROTECT 21  
MI 58  
CSC 54  
CSCI 19  
IA 8  
CODEC 91  
TELECOM 20

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Interinstitutional File:  
2022/0272(COD)

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#### NOTE

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| From:           | Presidency  |
| To:             | Delegations   |
| No. prev. doc.: | 15037/1/22 REV 1  |
| No. Cion doc.:  | 12429/22 + ADD 1-6  |
| 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) 2019/102: Articles 5, 10 - 17 and annexes I and II<br>- revised Presidency compromise proposal |

Member States will find in Annex a revised Presidency compromise proposal on the provisions regarding obligations of economic operators and essential requirements - (Art 5 and Art 10-17, Annexes I and II, including essential requirements and reporting obligations. This compromise proposal is based on the outcome of discussions during the HWPCI meetings 13 January 2023 and written comments received from Member States. This proposal will be presented and discussed at the HWPCI meeting on 1 February 2023. Changes compared to the Commission proposal are indicated in **bold** and ~~striketrough~~.

*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, updated, and
- (2) the processes put in place by the manufacturer comply with the essential requirements set out in Section 2 of Annex I.

*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.

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<sup>1</sup> when integrating components sourced from third parties ~~in products with digital elements~~ **in a manner that such components do not compromise the security of the product with digital elements. They shall ensure that such components do not compromise the security of the product with digital elements.**
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 ~~they~~ **it** becomes aware of and any relevant information provided by third parties, and, where applicable, update the **cybersecurity** risk assessment of the product.
6. ~~When placing a product with digital elements on the market, and for the expected product lifetime or for a period of five years from the placing of the product on the market, whichever is shorter, m~~**Manufacturers shall ensure, when placing a product with digital elements on the market and for a period of time after the placing on the market appropriate to the type of product and its expected lifetime, that vulnerabilities of that product are handled effectively and in accordance with the essential requirements set out in Section 2 of Annex I.**

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<sup>1</sup> Recital to be added

**Manufacturers shall determine the period of time referred to in the first subparagraph of this paragraph taking into account the time users reasonably expect to receive security updates given the product's functionality and intended purpose. For products with digital elements that have a lifetime of more than five years, the period of time determined by the manufacturers referred to in the first subparagraph of this paragraph shall be no less than five years.**

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.

**Manufacturers shall specify, at the time of the placing on the market, in an easily accessible manner and where applicable on the packaging of the product with digital elements, the month and year by which the technical security support, as referred in Annex II, point (8), ends.**

**Security updates, referred to in Section 2, point (8), of Annex I, shall remain available for a minimum duration of 10 years.**

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, ~~where relevant~~, at the disposal of the market surveillance authorities for ten years 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 19 by reference to which the conformity of the product with digital elements is declared or by application of which its conformity is verified.
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. They shall be clear, understandable, intelligible and legible. They shall allow for a secure installation, operation and use of the products with digital elements.
11. Manufacturers shall either provide the EU declaration of conformity with the product with digital elements or include in the instructions and information set out in Annex II the internet address at which the EU declaration of conformity can be accessed.
12. From the placing on the market and for the **period of time referred to in paragraph 6** ~~expected product lifetime or for a period of five years after the placing on the market of a product with digital elements, whichever is shorter~~, 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, 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).

#### *Article 11*

##### *Reporting obligations of manufacturers*

1. The manufacturer shall, without undue delay and in any event within 24 hours of becoming aware of it, notify **to the CSIRTs designated as coordinators for the purposes of coordinated vulnerability disclosure in accordance with** ~~pursuant to Article [Article X]~~ **12(1) of Directive [Directive XXX/XXXX (NIS2)](EU) 2022/2555 of Member States concerned [through a single reporting platform] to ENISA** any actively exploited vulnerability contained in the product with digital elements. The notification shall include **technical** details concerning that vulnerability and, where applicable, any corrective or mitigating measures taken.

~~ENISA~~ The CSIRTs shall, without undue delay, unless for **justified** cybersecurity risk-related grounds, forward the notification to ~~ENISA the CSIRT designated for the purposes of coordinated vulnerability disclosure in accordance with Article [Article X] of Directive [Directive XXX/XXXX (NIS2)] of Member States concerned upon receipt~~ and inform the market surveillance authorities of all the concerned Member States ~~y~~ about the notified vulnerability.

2. The manufacturer shall, without undue delay and in any event within 24 hours of becoming aware of it, notify ~~to ENISA the single point of contact designated or established in accordance with~~ pursuant to Article ~~[Article X]~~8(3) of Directive (EU) 2022/2555 ~~[Directive XXX/XXXX (NIS2)]~~ of the Member States concerned [through a single reporting platform] any incident<sup>2</sup> having impact on the security of the product with digital elements. ~~ENISA The designated single point of contact~~ shall, without undue delay, unless for **justified** cybersecurity risk-related grounds, forward the notifications to ~~the single point of contact designated in accordance with Article [Article X] of Directive [Directive XXX/XXXX (NIS2)] of the Member States concerned~~ ENISA and inform the market surveillance authorities in all concerned Member States about the notified incidents. The incident notification shall include information on the severity and impact of the incident and, where applicable, indicate whether the manufacturer suspects the incident to be caused by unlawful or malicious acts or considers it to have a cross-border impact.
3. ENISA shall submit to the European cyber crisis liaison organisation network (EU-CyCLONe) established ~~by~~under Article ~~[Article X]~~16 of Directive (EU) 2022/2555 ~~[Directive XXX/XXXX (NIS2)]~~ information notified pursuant to paragraphs 1 and 2 if such information is relevant for the coordinated management of large-scale cybersecurity incidents and crises at an operational level.
4. The manufacturer shall inform, without undue delay and after becoming aware, the users of the product with digital elements about the incident and, where necessary, about corrective measures that the user can deploy to mitigate the impact of the incident.

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<sup>2</sup> Definition will be added

5. The Commission may, by means of implementing acts, specify further the type of information, format and procedure of the notifications submitted pursuant to paragraphs 1 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).
6. ENISA, on the basis of the notifications received pursuant to paragraphs 1 and 2, shall 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~~ **established under Article [Article X] 14 of Directive (EU) 2022/2555 [Directive XXX/XXXX (NIS2)]**. The first such report shall be submitted within 24 months after the obligations laid down in paragraphs 1 and 2 start applying.
7. 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 maintaining the component.

## *Article 12*

### *Authorised representatives*

1. A manufacturer may appoint an authorised representative ~~by a written mandate~~.
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. 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 ten years after the product with digital elements has been placed on the market;



- 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 **cybersecurity** 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 information and instructions for use as set out in Annex II.
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 the essential requirements set out in Annex I, 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 the essential requirements set out in Annex I. 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.

4. Importers shall indicate their name, registered trade name or registered trademark, the postal address and **website**, ~~the~~ email address **or other digital contact** at which they can be contacted on the product with digital elements or, where that is not possible, 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 shall ensure that the product with digital elements is accompanied by the instructions and information set out in Annex II in a language which can be easily understood by users.
6. Importers who know or have reason to believe that a product with digital elements, which they have placed on the market, or the processes put in place by its 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 processes put in place by its manufacturer into conformity with the essential requirements set out in Annex I, or to withdraw or recall the product, if appropriate.

Upon identifying 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.

7. Importers shall, for ten years after the product with digital elements has been placed on the market, 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.

8. 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.
9. 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(10),10(11) and 13(4).

3. Where a distributor 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 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 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 the essential requirements set out in Annex I 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 identifying 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 the essential requirements set out in 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 made available on the market.

6. When the distributor 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 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 the obligations of the manufacturer set out in Articles 10 and 11(1), (2), (4) and (7) 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 shall be considered a manufacturer for the purposes of this Regulation.

That person shall be subject to the obligations of the manufacturer set out in Articles 10 and 11(1), (2), (4) and (7), 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 and where the information is available, 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;
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.

**ESSENTIAL CYBERSECURITY REQUIREMENTS**

**1. 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 enable an appropriate level of cybersecurity based on the risks;
- ~~(2) Products with digital elements shall be delivered without any known exploitable vulnerabilities;~~
- (3) On the basis of the **cybersecurity** risk assessment referred to in Article 10(2) and where applicable, products with digital elements shall:
  - (aa) be placed on the market without any known vulnerabilities;**
  - (a) be **placed on the market** with a secure by default configuration, including the possibility to reset the product to its original state;
  - (b) ensure protection from unauthorised access by appropriate control mechanisms, including but not limited to authentication, identity or access management systems;
  - (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;
  - (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 use of the product ('minimisation of data');

- (f) protect the availability of essential functions, including the resilience against and mitigation of denial of service attacks;
- (g) minimise their own negative impact 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;
- (k) **ensure-enable** that vulnerabilities can be addressed through security updates, including, where applicable, through automatic updates the notification of available updates to users.

## 2. 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;
- (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, publically 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 user friendly** information helping users to remediate the vulnerabilities;
- (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 **exploitable** vulnerabilities are fixed or mitigated in a timely manner;
- (8) ensure that, where security ~~patches or~~ updates are available to address identified security issues, they are disseminated without delay and free of charge, accompanied by advisory messages providing users with the relevant information, including on potential action to be taken.

**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 and the email address at which the manufacturer can be contacted, on the product or, where that is not possible, on its packaging or in a document accompanying the product;
2. the point of contact where information about cybersecurity vulnerabilities of the product can be reported and received;
3. the correct identification of the type, batch, version or serial number or other element allowing the identification of the product and the corresponding instructions and user information;
4. the intended use, 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;
6. if and, where applicable, where the software bill of materials can be accessed;
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 until when it will be provided, at the very least until when users can expect 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.
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