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NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	15037/1/22 REV 1
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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 - revised Presidency compromise proposal

Member States will find in Annex a revised Presidency compromise proposal on the provisions regarding the scope of the Cyber Resilience Act, based on the outcome of discussions during the HWPCI meetings on 5 and 19 October, 23 November as well as on 7 December 2022 and written comments received from Member States. This proposal will be presented and discussed at the HWPCI meeting on 18 January 2023. Changes compared to the Commission proposal are indicated in **bold**. The latest changes compared to the previous version are in **bold** and underlined.

(9) This Regulation ~~ensures a high level of cybersecurity of products with digital elements. It does not regulate services, such as Software-as-a-Service (SaaS), except for~~ applies to remote data processing solutions relating to a product with digital elements, ~~understood~~ defined as any data processing at a distance for which the software **or hardware** is designed and developed by the manufacturer of the product concerned or under the responsibility of that manufacturer, and the absence of which would prevent such a product with digital elements from performing one of its functions. **Software-as-a-Service (SaaS) solutions constitute remote data processing solutions within the meaning of this Regulation only if they meet that definition. For example, 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. In addition, websites would not constitute remote data processing solutions of web browsers since they are not developed under the responsibility of a browser manufacturer and as the absence of any individual website would not prevent a browser from performing its functions.** [Directive XXX/XXXX (NIS2)] puts in place cybersecurity and incident reporting requirements for essential and important entities, such as critical infrastructure, with a view to increasing the resilience of the services they provide. [Directive XXX/XXXX (NIS2)] applies to cloud computing services and cloud service models, such as SaaS. All entities providing cloud computing services in the Union that meet or exceed the threshold for medium-sized enterprises fall in the scope of that Directive.

(New recital corresponding to Art 4, para 1)

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. 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 from national markets, that take account of non-technical factors. National measures relating to such factors must comply with Union law.

(New recital corresponding to Art 4, para 3b):

This Regulation should be without prejudice to the Member States' prerogatives to take measures safeguarding national security, in compliance with Union law. Member States should be able to subject products with digital elements that will be used for military, defence or national security purposes, to additional measures.

(New recital):

The obligations laid down in this Regulation should not entail the supply of information the disclosure of which would be contrary to the essential interests of Member States' security.

Article 2

Scope

1. This 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.
2. This Regulation does not apply to products with digital elements to which the following Union acts apply:
 - (a) Regulation (EU) 2017/745;
 - (b) Regulation (EU) 2017/746;
 - (c) Regulation (EU) 2019/2144
 - ~~[(d) Directive (EU) 2005/44/EC];~~

3. This Regulation does not apply to products with digital elements that have been certified in accordance with Regulation (EU) 2018/1139.
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 amend this Regulation specifying whether such limitation or exclusion is necessary, the concerned products and rules, as well as the scope of the limitation, if relevant.

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

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 **or hardware** 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;
- (6) ‘software’ means the **logical** 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;
- (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;
- (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;

(xx) ‘recall’ means recall as defined in Article 3, point (22) of Regulation (EU) 2019/1020;

(xx) ‘withdrawal’ means withdrawal as defined in Article 3, point (23) of Regulation (EU) 2019/1020.

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.
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 specified under other Union harmonisation legislation.**
- 5. This Regulation shall not prevent Member States from subjecting products with digital elements to additional measures when these specific products will be used for military, defence or national security purposes, and such measures are necessary and proportionate ~~and necessary~~ for the achievement of those purposes.**