



Council of the European Union
General Secretariat

**Interinstitutional files:
2022/0272 (COD)**

Brussels, 06 March 2023

WK 2555/2023 ADD 2

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NOTE

From:	General Secretariat of the Council
To:	Delegations
N° Cion doc.:	12429/ 2022 + 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) 2019/1020: Delegations' comments on Block 4

Delegations will find attached additional comments by the German delegation on the above-mentioned legislative proposal.

Article 9

Machinery products

Machinery products under the scope of Regulation [Machinery Regulation proposal] which are products with digital elements within the meaning of this Regulation ~~and for which an EU declaration of conformity has been issued on the basis of this Regulation~~ shall be deemed to be in conformity with the **requirements related to cybersecurity regarding the protection against corruption and safety and reliability of control systems** ~~essential health and safety requirements~~ set out in **Sections 1.1.9 and 1.2.1 of** Annex [Annex III, ~~Sections 1.1.9 and 1.2.1~~] to Regulation [Machinery Regulation proposal], as regards ~~protection against corruption and safety and reliability of control systems, and in so far as~~ **if** the achievement of the level of **cybersecurity** protection required by **under** those requirements **Sections** is demonstrated in the EU declaration of conformity issued ~~under~~ **pursuant to** 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 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 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 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 reasons to consider that a product with digital elements, including its vulnerability handling, presents a significant cybersecurity risk, it shall carry out 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 ~~it~~ **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 ~~appropriate~~ corrective actions.

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 ~~manufacturer~~ **economic operator** shall ensure that ~~all~~ **any** 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.

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 54 a)

Amendment to Regulation (EU) 2020/1828

In Annex 1 to Regulation (EU) 2020/1828 the following point is added:

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