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From:	Presidency
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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) 2019/1020: Articles 7-9 and 25-57 - Presidency compromise proposal

Delegations will find in the Annex a Presidency compromise proposal on the provisions regarding:

- Articles 7-9: interplay with other legal acts,
- Articles 25-40: notification of conformity assessment bodies,
- Articles 41-49: market surveillance and enforcement,
- Articles 50-51: delegated powers and committee procedure,
- Articles 52-53: confidentiality and penalties, and
- Articles 54-57: transitional and final provisions.

The compromise proposal is based on the outcome of discussions during the HWPCI meeting on 15 February and written comments received from the Member States. It will be presented and discussed at the HWPCI meeting on 1st March 2023. Changes compared to the Commission proposal are indicated in **bold** and ~~strikethrough~~.

Article 7

General product safety

By way of derogation from Article 2(1), third subparagraph, point (b), of Regulation [General Product Safety Regulation], **Chapter III, Section 1, Chapters V and VII, and Chapters IX to XI of that Regulation shall apply to products with digital elements with respect to safety risks not covered by this Regulation** where **those** products with digital elements are not subject to specific requirements laid down in other Union harmonisation legislation within the meaning of [Article 3, point (25) of the General Product Safety Regulation], ~~Chapter III, Section 1, Chapters V and VII, and Chapters IX to XI of Regulation [General Product Safety Regulation]~~ shall apply to those products with respect to safety risks not covered by this Regulation.

Article 8

High-risk AI systems

1. **Without prejudice to the requirements relating to accuracy and robustness set out in Article [Article 15] Products with digital elements classified as high-risk AI systems in accordance with Article [Article 6] of Regulation [the AI Regulation], products with digital elements** which fall within the scope of this Regulation, **and which are classified as high-risk AI systems pursuant to Article [Article 6] of Regulation [the AI Regulation]** and fulfil the essential requirements set out in Section 1 of Annex I of this Regulation, and where the processes put in place by the manufacturer are compliant with the essential requirements set out in Section 2 of Annex I, shall be deemed in compliance with the **cybersecurity** requirements related to cybersecurity set out in Article [Article 15] of **that** Regulation [the AI Regulation], without prejudice to the other requirements related to accuracy and robustness included in the aforementioned Article, and in so far as the achievement of the level of protection required by those requirements is demonstrated by the EU declaration of conformity issued under this Regulation. **if:**

- (a) they fulfil the essential requirements set out in Section 1 of Annex I to this Regulation;
- (b) the processes put in place by the manufacturer are compliant with the essential requirements set out in Section 2 of Annex I to this Regulation; and
- (c) the achievement of the level of cybersecurity protection required under Article [Article 15] of Regulation [the AI Regulation] is demonstrated in the EU declaration of conformity issued under this Regulation.

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

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.~~

CHAPTER IV

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 25

Notification

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

Article 26

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 31.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in [Article 27] of this Regulation. In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 27

Requirements relating to notifying authorities

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

5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 28

Information obligation on notifying authorities

1. Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.
2. The Commission shall make that information publicly available.

Article 29

Requirements relating to notified bodies

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

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

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

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

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

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks referred to in Annex VI and in relation to which it has been notified, regardless of whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

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

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

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

7. The personnel responsible for carrying out conformity assessment activities shall have the following:
- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - (c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of its implementing acts;
 - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex VI or any provision of national law giving effect to it, except in relation to the market surveillance authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected. The conformity assessment body shall have documented procedures ensuring compliance with this paragraph.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 40 and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.
12. Conformity assessment bodies shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, in particular taking into account the interests of SMEs in relation to fees.

Article 30

Presumption of conformity of notified bodies

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

Article 31

Subsidiaries of and subcontracting by notified bodies

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

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

Article 32

Application for notification

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

Article 33

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies, which have satisfied the requirements laid down in Article 29.
2. The notifying authority shall notify the Commission and the other Member States using the New Approach Notified and Designated Organisations (NANDO) information system developed and managed by the Commission.

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

Only such a body shall be considered a notified body for the purposes of this Regulation.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 34

Identification numbers and lists of notified bodies

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

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been allocated to them and the activities for which they have been notified.

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

Article 35

Changes to notifications

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

Article 36

Challenge of the competence of notified bodies

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

Article 37

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Article 24 and Annex VI.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
3. Notified bodies shall however respect the degree of rigour and the level of protection required for the compliance of the product with the provisions of Regulation.
4. Where a notified body finds that requirements laid down in Annex I or in corresponding harmonised standards or in common specifications as referred to in Article 19 have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a ~~conformity~~ certificate **of conformity**.
5. Where, in the course of the monitoring of conformity following the issuance of a certificate, a notified body finds that a product no longer complies with the requirements laid down in this Regulation, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
6. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article X

Appeal against decisions of notified bodies

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

Article 38

Information obligation on notified bodies

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

Article 39

Exchange of experience

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

Article 40

Coordination of notified bodies

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

CHAPTER V

MARKET SURVEILLANCE AND ENFORCEMENT

Article 41

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

1. Regulation (EU) 2019/1020 shall apply to the products with digital elements within the scope of this Regulation.
2. Each Member State shall designate one or more market surveillance authorities for the purpose of ensuring the effective implementation of this Regulation. Member States may designate an existing or new authority to act as market surveillance authority for this Regulation.
3. Where relevant, the market surveillance authorities shall cooperate with the national cybersecurity certification authorities designated under Article 58 of Regulation (EU) 2019/881 and exchange information on a regular basis. With respect to the supervision of the implementation of the reporting obligations pursuant to Article 11 of this Regulation, the designated market surveillance authorities shall cooperate with ENISA.

4. Where relevant, the market surveillance authorities shall cooperate with other market surveillance authorities designated on the basis of other Union harmonisation legislation for other products, and exchange information on a regular basis.
5. Market surveillance authorities shall cooperate, as appropriate, with the authorities supervising Union data protection law. Such cooperation includes informing these authorities of any finding relevant for the fulfilment of their competences, including when issuing guidance and advice pursuant to paragraph 8 of this Article if such guidance and advice concerns the processing of personal data.

Authorities supervising Union data protection law shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of their tasks. They shall inform the designated market surveillance authorities of the Member State concerned of any such request.

6. Member States shall ensure that the designated market surveillance authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation.
7. The Commission shall facilitate the exchange of experience between designated market surveillance authorities.
8. Market surveillance authorities may provide guidance and advice to economic operators on the implementation of this Regulation, with the support of the Commission.
9. The market surveillance authorities shall report to the Commission on an annual basis the outcomes of relevant market surveillance activities. The designated market surveillance authorities shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union competition law.

10. For products with digital elements in the scope of this Regulation classified as high-risk AI systems according to Article [Article 6] of the Regulation [the AI Regulation], the market surveillance authorities designated for the purposes of the Regulation [the AI Regulation] shall be the authorities responsible for market surveillance activities required under this Regulation. The market surveillance authorities designated pursuant to Regulation [the AI Regulation] shall cooperate, as appropriate, with the market surveillance authorities designated pursuant to this Regulation and, with respect to the supervision of the implementation of the reporting obligations pursuant to Article 11, with ENISA. Market surveillance authorities designated pursuant to Regulation [the AI Regulation] shall in particular inform market surveillance authorities designated pursuant to this Regulation of any finding relevant for the fulfilment of their tasks in relation to the implementation of this Regulation.
11. A dedicated administrative cooperation group (ADCO) shall be established for the uniform application of this Regulation, pursuant to Article 30(2) of Regulation (EU) 2019/1020. This ADCO shall be composed of representatives of the designated market surveillance authorities and, if appropriate, representatives of single liaison offices.

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.

4. Where the ~~manufacturer~~ **economic operator** of a product with digital elements does not take adequate corrective action within the period referred to in paragraph 1, second subparagraph, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict that product **with digital elements from** being made available on its national market, to withdraw it from that market or to recall it.

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

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant products with digital elements, the origin of ~~the~~ **that** product with digital elements, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant **economic** operator. In particular, the market surveillance authority shall indicate whether the non-compliance is due to one or more of the following:

- (a) a failure of the product **with digital elements** or of the processes put in place by the manufacturer to meet the essential requirements set out in Annex I;
- (b) shortcomings in the harmonised standards, cybersecurity certification schemes, or common specifications, referred to in Article 18.

6. The market surveillance authorities of the Member States other than the market surveillance authority of the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product **with digital elements** concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within three months of receipt of the ~~information~~ **notification** referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified. This is without prejudice to the procedural rights of the **economic** operator concerned in accordance with Article 18 of Regulation (EU) 2019/1020.
8. The market surveillance authorities of all Member States shall ensure that appropriate restrictive measures are taken in respect of the product **with digital elements** concerned, such as withdrawal of ~~the~~ product from their market, without delay.

Article 44

Union safeguard procedure

1. Where, within three months of receipt of the notification referred to in Article 43(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union ~~legislation~~ **law**, the Commission shall without delay enter into consultation with the relevant Member State and the economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within nine months from the notification referred to in Article 43(4) and notify ~~such~~ **that** decision to the Member State concerned.
2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant product with digital elements is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.
3. Where the national measure is considered justified and the non-compliance of the product with digital elements is attributed to shortcomings in the harmonised standards, the Commission shall apply the procedure provided for in Article ~~40~~ **11** of Regulation (EU) No 1025/2012.

4. Where the national measure is considered justified and the non-compliance of the product with digital elements is attributed to shortcomings in a European cybersecurity certification scheme as referred to in Article 18, the Commission shall consider whether to amend or repeal the implementing act as referred to in Article 18(4) that specifies the presumption of conformity concerning that certification scheme.
5. Where the national measure is considered justified and the non-compliance of the product with digital elements is attributed to shortcomings in common specifications as referred to in Article 19, the Commission shall consider whether to amend or repeal the implementing act referred to in Article 19 setting out those common specifications.

Article 45

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

1. Where the Commission has sufficient reasons to consider, including based on information provided by ENISA, that a product with digital elements that presents a significant cybersecurity risk is non-compliant with the requirements laid down in this Regulation, it may request the relevant market surveillance authorities to carry out an evaluation of compliance and follow the procedures referred to in Article 43.
2. In exceptional circumstances which justify an immediate intervention to preserve the good functioning of the internal market and where the Commission has sufficient reasons to consider that the product **with digital elements** referred to in paragraph 1 remains non-compliant with the requirements laid down in this Regulation and no effective measures have been taken by the relevant market surveillance authorities, the Commission may request ENISA to **provide an analysis to support** ~~carry out~~ an evaluation of compliance. The Commission shall inform the relevant market surveillance authorities accordingly. The relevant economic operators shall cooperate as necessary with ENISA.

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

Article 46

Compliant products with digital elements which present a significant cybersecurity risk

- 1. The market surveillance authority of a Member State shall require an economic operator to take appropriate measures where, having performed an evaluation under Article 43, it finds that although a product with digital elements and the processes put in place by the manufacturer are in compliance with this Regulation, it presents a significant cybersecurity risk as well as a risk to:**

- (a) the health or safety of persons;
- (b) the compliance with obligations under Union or national law intended to protect fundamental rights;
- (c) the availability, authenticity, integrity or confidentiality of services offered using an electronic information system by entities of a type referred to in Annex I to Directive (EU) 2022/2555; or
- (d) other aspects of public interest protection.

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

1. ~~Where, having performed an evaluation under Article 43, the market surveillance authority of a Member State finds that although a product with digital elements and the processes put in place by the manufacturer are in compliance with this Regulation, they present a significant cybersecurity risk and, in addition, they pose a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights, the availability authenticity, integrity or confidentiality of services offered using an electronic information system by essential entities of the type referred to in [Annex I to Directive XXX / XXXX (NIS2)] or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the product with digital elements and the processes put in place by the manufacturer concerned, when placed on the market, no longer present that risk, to withdraw the product with digital elements from the market or to recall it within a reasonable period, commensurate with the nature of the risk.~~

2. The manufacturer or other relevant **economic** operators shall ensure that corrective action is taken in respect of the products with digital elements concerned that they have made available on the market throughout the Union within the timeline established by the market surveillance authority of the Member State referred to in paragraph 1.
3. The Member State shall immediately inform the Commission and the other Member States about the measures taken pursuant to paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the products with digital elements concerned, the origin and the supply chain of those products with digital elements, the nature of the risks involved and the nature and duration of the national measures taken.
4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.
5. — The Commission shall address its decision to the Member States.
6. Where the Commission has sufficient reasons to consider, including based on information provided by ENISA, that a product with digital elements, although compliant with this Regulation, presents the risks referred to in paragraph 1, it may request the relevant market surveillance authority or authorities to carry out an evaluation of ~~compliance~~ **the risks** and follow the procedures referred to in Article 43 and paragraphs 1, 2 and 3 of this Article.
7. In exceptional circumstances which justify an immediate intervention to preserve the good functioning of the internal market and where the Commission has sufficient reasons to consider that the product **with digital elements** referred to in paragraph 6 continues to present the risks referred to in paragraph 1, and no effective measures have been taken by the relevant national market surveillance authorities, the Commission may request ENISA to **provide an analysis to support** ~~carry out~~ an evaluation of the risks presented by that product **with digital elements** and shall inform the relevant market surveillance authorities accordingly. The relevant economic operators shall cooperate as necessary with ENISA.

8. Based on ~~ENISA's~~ **the** evaluation referred to in paragraph 7, the Commission may establish that a corrective or restrictive measure is necessary at Union level. To this end, it shall without delay consult the Member States concerned and the relevant **economic** operator or operators.
9. On the basis of the consultation referred to in paragraph 8, the Commission may adopt implementing acts to decide on corrective or restrictive measures at Union level, including ordering withdrawal **of the product with digital elements** from the market, or recalling **of it**, within a reasonable period, commensurate with the nature of the risk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).
10. The Commission shall immediately communicate the ~~decision~~ **implementing acts** referred to in ~~the~~ paragraph 9 to the relevant **economic** operator or operators. Member States shall implement ~~such~~ **those** acts without delay and shall inform the Commission accordingly.
11. Paragraphs 6 to 10 shall apply for the duration of the exceptional situation that justified the Commission's intervention and for as long as the ~~respective product~~ **with digital elements concerned** continues to present the risks referred to in paragraph 1.

Article 47

Formal non-compliance

1. Where the market surveillance authority of a Member State makes one of the following findings, it shall require the relevant manufacturer to end to the non-compliance concerned:
- (a) the ~~conformity~~ **CE** marking has been affixed in violation of Articles 21 and 22;
 - (b) the ~~conformity~~ **CE** marking has not been affixed;
 - (c) the EU declaration of conformity has not been drawn up;

- (d) the EU declaration of conformity has not been drawn up correctly;
 - (e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;
 - (f) the technical documentation is either not available or not complete.
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product with digital elements from being made available on the market or ensure that it is recalled or withdrawn from the market.

Article 48

Joint activities of market surveillance authorities

1. Market surveillance authorities may agree with other relevant authorities to carry out joint activities aimed at ensuring cybersecurity and protection of consumers with respect to specific products with digital elements placed **on the market** or made available on the market, in particular products **with digital elements** that are often found to present cybersecurity risks.
2. The Commission or ENISA may propose joint activities for checking compliance with this Regulation to be conducted by market surveillance authorities based on indications or information of potential non-compliance across several Member States of products **with digital elements** falling in the scope of this Regulation with the requirements laid down by ~~the latter~~ **herein**.
3. The market surveillance authorities and, **where applicable**, the Commission, ~~where applicable~~, shall ensure that the agreement to carry out joint activities does not lead to unfair competition between economic operators and does not negatively affect the objectivity, independence and impartiality of the parties to the agreement.

4. A market surveillance authority may use any information resulting from the **joint** activities carried out as part of any investigation that it undertakes.
5. The market surveillance authority concerned and, **where applicable**, the Commission; ~~where applicable~~, shall make the agreement on joint activities, including the names of the parties involved, available to the public.

Article 49

Sweeps

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

CHAPTER VI

DELEGATED POWERS AND COMMITTEE PROCEDURE

Article 50

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 2(4), Article 6(2), Article 6(3), Article 6(5), Article 20(5) and Article 23(5) shall be conferred on the Commission¹.
3. The delegation of power referred to in Article 2(4), Article 6(2), Article 6(3), Article 6(5), Article 20(5) and Article 23(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

¹ Timeframe will be added.

6. A delegated act adopted pursuant to Article 2(4), Article 6(2), Article 6(3), Article 6(5), Article 20(5) and Article 23(5) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 51

Committee procedure

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

CHAPTER VII

CONFIDENTIALITY AND PENALTIES

Article 52

Confidentiality

1. All parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:
 - (a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 of the European Parliament and of the Council²;
 - (b) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;
 - (c) public and national security interests;
 - (d) integrity of criminal or administrative proceedings.
2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the market surveillance authorities and between market surveillance authorities and the Commission shall not be disclosed without the prior agreement of the originating market surveillance authority.

² Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law of the Member States.
4. The Commission and Member States may exchange, where necessary, sensitive information with relevant authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of protection.

Article 53

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of this Regulation and shall take all measures necessary to ensure that they are ~~enforced~~**implemented**. The penalties provided for shall be effective, proportionate and dissuasive.
2. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it without delay of any subsequent amendment affecting them.
3. The non-compliance with the essential cybersecurity requirements laid down in Annex I and the obligations set out in Articles 10 and 11 shall be subject to administrative fines of up to 15 000 000 EUR or, if the offender is an undertaking, up to 2.5 % of the its total worldwide annual turnover for the preceding financial year, whichever is higher.
4. The non-compliance with ~~any other~~**the** obligations **set out in Articles [Articles12; 13; 14; 15; 16; 17; 20; 22 (1)-(4); 23 (1)-(4); 24(1)-(3); 29; 31; 37; 38; 42]** under this Regulation shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is an undertaking, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

5. The supply of incorrect, incomplete or misleading information to notified bodies and market surveillance authorities in reply to a request shall be subject to administrative fines of up to 5 000 000 EUR or, if the offender is an undertaking, up to 1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.
6. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:
- (a) the nature, gravity and duration of the infringement and of its consequences;
 - (b) whether administrative fines have been already applied by other market surveillance authorities to the same **economic** operator for a similar infringement;
 - (c) the size and market share of the **economic** operator committing the infringement.
7. Market surveillance authorities that apply administrative fines shall ~~share~~ **communicate** this ~~to information with~~ the market surveillance authorities of other Member States through the information and communication system referred to in Article 34 of Regulation (EU) 2019/1020.
8. Each Member State shall lay down rules on whether and to what extent administrative fines may be imposed on public authorities and **public** bodies established in that Member State.
9. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts or other bodies according to the competences established at national level in those Member States. The application of such rules in those Member States shall have an equivalent effect.

10. Administrative fines may be imposed, depending on the circumstances of each individual case, in addition to any other corrective or restrictive measures applied by the market surveillance authorities for the same infringement.

CHAPTER VIII

TRANSITIONAL AND FINAL PROVISIONS

Article 54

Amendment to Regulation (EU) 2019/1020

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

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

Article 55

Transitional provisions

1. EU type-examination certificates and approval decisions issued regarding cybersecurity requirements for products with digital elements that are subject to other Union harmonisation legislation shall remain valid until [42 months after the date of entry into force of this Regulation], unless they expire before that date, or unless otherwise specified in other Union legislation, in which case they shall remain valid as referred to in that Union legislation.
2. Products with digital elements that have been placed on the market before [date of application of this Regulation referred to in Article 57], shall be subject to requirements of this Regulation only if, from that date, those products are subject to substantial modifications ~~in their design or intended purpose~~.

3. By way of derogation from paragraph 2, the obligations laid down in Article 11 shall apply to all products with digital elements within the scope of this Regulation that have been placed on the market before [date of application of this Regulation referred to in Article 57].

Article 56

Evaluation and review

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

Article 57

Entry into force and application

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

It shall apply from [24 months after the date of entry into force of this Regulation]. However Article 11 shall apply from [12 months after the date of entry into force of this Regulation].