EUROPEAN
COMMISSION

Brussels, XXX
[…](2026) XXX draft

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a framework for product compliance, accreditation, and market surveillance and repealing Decision No 768/2008/EC, Regulation (EC) No 765/2008 and Regulation (EU) 2019/1020

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Decision 768/2008 on a common framework for the marketing of products, Regulation 765/2008 on accreditation, and Regulation (EU) 2019/1020 on market surveillance were conceived for a market that has since changed profoundly. Products, manufacturing processes and value chains have become increasingly digitalised, interconnected and complex, while the transition towards a circular economy has given rise to new business models, including refurbishment and remanufacturing that the current rules do not adequately capture. The present framework continues to rely largely on paper-based compliance which limits the accessibility, searchability and interoperability of compliance product information and the analogue CE marking does not allow for direct, verifiable digital product compliance data to be verified digitally. At the same time, the rapid exponential growth of e-commerce and the emergence of refurbished, remanufactured and other circular-economy business models have created, in particular through online marketplaces and distance sales originating in third countries, significant gaps in the allocation of responsibilities along supply chains, among economic operators, resulting in legal uncertainty and, uneven enforcement. and an unlevel playing field between compliant and non-compliant operators. These developments have also shed light on significant shortcomings affecting market surveillance in the Union: important regulatory loopholes that hinder the enforcement actions of national market surveillance authorities, in particular vis-à-vis e-commerce, a subpar market surveillance capacity across the Union, and an imperfect cooperation between relevant authorities, within and between Member States.

Against this background, the proposal seeks to modernise and future-proof the Union's horizontal framework for product compliance. It does so by enabling the digitalisation of product information through the introduction of a Digital Product Passport and a digital CE marking; by clarifying and reinforcing the obligations of economic operators and online marketplaces, across increasingly complex and cross-border supply chains; by strengthening the oversight of notified bodies to ensure the reliability of conformity assessment; by reinforcing safeguard procedures against unsafe or non-compliant products; by closing regulatory loopholes hindering enforcement; by boosting the capacity to carry out market surveillance throughout the Union; and by enhancing cross-border cooperation between market surveillance and customs authorities, so as to ensure effective and uniform enforcement of Union harmonisation legislation across the internal market.

• Consistency with existing policy provisions in the policy area

This proposal forms an integral part of the European Product Package. It is closely aligned with, and complements, the parallel revision of the Regulation on European standardisation ensuring that the two initiatives together provide a consistent and proportionate legal framework covering the entire product lifecycle, from the design of products, including the development of the related harmonised standards, to the placing of those products on the market, their traceability and, where applicable, their refurbishment or remanufacturing.

By consolidating and updating the common horizontal rules currently laid down in Decision 768/2008 on a common framework for the marketing of products, Regulation 765/2008 on accreditation, and Regulation (EU) 2019/1020 on market surveillance, into a single Regulation, this proposal ensures greater coherence and consistency across the 29 sectoral acts of Union harmonisation legislation that currently rely on this horizontal framework. This consolidation avoids the unnecessary duplication and divergence that has arisen from the repeated incorporation of common provisions into sectoral legislation, thereby preserving the integrity

of the internal market for products and safeguarding legal certainty for economic operators, in particular those active across borders.

- **Consistency with other Union policies**

The initiative dovetails with other Union policies, notably the Circular Economy Action Plan, the Digital Single Market strategy and the EU's consumer-protection and environmental objectives, by fostering safer, more sustainable and more competitive product flows throughout the Single Market. The initiative is closely related to the General Product Safety Regulation ensuring the compliance of non-harmonised consumer products. The European Product Act ensures consistency with certain existing provisions of the General Product Safety Regulation, notably those related to obligations of providers of online marketplaces, and introduces new market surveillance mechanisms that, for coherence purposes, will also apply to non-harmonised products. In addition, the European Product Act and the upcoming revised Union Customs Code complement each other to ensure effective controls and compliance checks on products entering the Union market from third countries. They jointly aim to equip the Union with a more modern toolbox to deal with trends such as huge increases in trade volumes, especially in e-commerce. Finally, the European Product Act complements the Digital Services Act by defining compliance-related obligations specific for providers of online marketplaces and operationalises certain DSA tools for the purpose of product compliance. Such coherence is achieved by using automated search tools and technologies, and ensuring that providers of online marketplaces are aware of non-compliant, and thus illegal, content.

This proposal further aligns the Union harmonisation legislation with the Union non-harmonisation legislation. This is achieved by amending the General Product Safety Regulation that will incorporate several new elements of the EPA including additional obligations for the responsible economic operator in the Union, the obligations for the fulfilment service providers and refurbishers, further obligations on the online market platforms, the digital product passport framework and the new provisions on the market surveillance section and on the penalties.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The legislative instrument is proposed as a regulation on the basis of Articles 33 and 114 of the Treaty on the Functioning of the European Union, which empowers the Union to adopt measures respectively to strengthen customs cooperation between Member States and between the latter and the Commission and for the approximation of the provisions laid down by the harmonised product legislation in order to ensure the functioning of the internal market.

- **Subsidiarity (for non-exclusive competence)**

The cross-border nature of modern supply chains, the prevalence of online marketplaces and the necessity for a harmonised digital product passport system make the action intrinsically supranational; national measures alone would risk fragmenting the market, creating enforcement gaps and duplicating effort, thereby contravening the principle of subsidiarity.

- **Proportionality**

The proposed measures are proportionate because they are carefully calibrated to address the identified weaknesses without imposing unnecessary burdens. Digital compliance tools are designed to be scalable and to reduce long-term administrative costs, while the clarification of responsibilities for circular operators and the reinforcement of notified body oversight target specific regulatory ambiguities.

- **Choice of the instrument**

The choice of a regulation rather than a directive ensures immediate, uniform applicability across all Member States, which is essential for the seamless exchange of product compliance data, the consistent enforcement of safety standards and the avoidance of divergent national implementations that could undermine the level playing field for enterprises of all sizes.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The 2022 REFIT evaluation of the New Legislative Framework (SWD(2022) 364) found the New Legislative Framework's core architecture to remain effective, but its relevance weakened by the digital and circular transitions and by increasingly complex value chains, and recommended that it be made more future-proof. A dedicated evaluation of the Market Surveillance Regulation (Regulation (EU) 2019/1020) was carried out alongside this initiative and accompanies this proposal.

That evaluation found that the Market Surveillance Regulation has only partly fulfilled its general objective of ensuring that only compliant products circulate on the Single Market, as the non-compliance rates of products checked by market surveillance authorities remain persistently high. While the Regulation expanded the regulatory toolbox available to market surveillance authorities, its practical implementation remains a challenge, in particular in what concerns distant sales and imports from third countries. Enforcement capacity remains insufficient and uneven across the Union while cross-border cooperation remains limited. The evaluation concluded that the Regulation's objectives remain relevant but that the problems it was designed to address have intensified, in particular for e-commerce and imports from third countries, and identified simplification potential through digitalisation, improved traceability of operators and better coordination among authorities.

- **Stakeholder consultations**

The consultation strategy covered the revision of the New Legislative Framework and the Market Surveillance Regulation, and combined a call for evidence, a 12-week open public consultation (12 November 2025 to 4 February 2026), an SME Panel survey, targeted surveys and interviews, and dedicated workshops, complemented by discussions with Member States and expert groups.

On the New Legislative Framework strand, the call for evidence received 133 responses, the public consultation 299 responses and 16 position papers, the SME Panel 39 responses, and the targeted consultation reached 1 841 stakeholders with 549 complete replies used in the assessment, supported by 85 interviews and a dedicated stakeholder workshop on the Digital Product Passport held on 24 June 2026. On the Market Surveillance Regulation strand, the call for evidence gathered 97 contributions and the public consultation 154 contributions from 22 countries, complemented by a validation workshop. Stakeholders broadly supported a targeted modernisation of the framework rather than a fundamental redesign, favoured digital-first compliance information provided accessibility is safeguarded, called for clearer rules for circular-economy operators, and identified the accountability of online marketplaces, controls on imports and the resourcing of market surveillance authorities as priority issues. On the architecture of the reform, 44% of public consultation respondents supported merging the New Legislative Framework, the Market Surveillance Regulation and the Standardisation Regulation into a single instrument and 28% disagreed; this evidence, together with the distinct institutional and financing logic of the Standardisation Regulation, supports the approach followed in this

proposal of merging the New Legislative Framework and the Market Surveillance Regulation into the European Product Act while keeping the Standardisation Regulation as a separate instrument.

- **Collection and use of expertise**

The impact assessment and the accompanying evaluations draw on complementary studies carried out by external contractors, who conducted the targeted consultation activities (surveys and interviews), systematically analysed the evidence gathered through the call for evidence and public consultation, and reinforced the findings through desk research. An interservice steering group chaired by DG GROW, involving the Secretariat-General, the Legal Service and the Directorates-General for Budget, Climate Action, Communications Networks Content and Technology, Competition, Digital Services, Energy, Environment, the Joint Research Centre, Justice and Consumers, Mobility and Transport, Taxation and Customs Union and Trade, met four times to steer the analysis. Additional expertise was drawn from the Commission's expert groups on market surveillance, notified bodies and administrative cooperation groups, the Single Liaison Officers, and the Fit for Future Platform, whose opinion fed into the evaluation of the New Legislative Framework.

The Regulatory Scrutiny Board was consulted informally in September 2025 and formally on 17 June 2026 on both impact assessments, and issued positive opinions with reservations; its recommendations, concerning in particular the evidentiary basis for the baseline, the robustness of the cost-benefit methodology and the granularity of stakeholder-specific findings, were addressed in the revised reports.

- **Impact assessment**

The impact assessment was carried out in line with the Commission's Better Regulation requirements and comprises two Staff Working Documents – one covering the revision of the New Legislative Framework, which underpins the EPA, and one back-to-back covering the revision of the Market Surveillance Regulation – both submitted to, and positively assessed with reservations by, the Regulatory Scrutiny Board on 17 June 2026. In the case of the New Legislative Framework, policy options were assessed against four specific objectives covering the digitalisation of compliance information, the accommodation of circularity and sustainability, the reliability of conformity assessment, and effective enforcement, using cost-benefit analysis complemented by a multi-criteria decision analysis (SOCRATES). In the case of the Market Surveillance Regulation, policy options were assessed against three specific objectives covering regulatory toolbox, enforcement capacity and coordination, using cost- a multi-criteria decision analysis (SOCRATES).

The preferred package underpinning the EPA combines the digitalisation of compliance information through the Digital Product Passport, clearer horizontal definitions and responsibilities for circular operators, reinforced oversight of notified bodies and accreditation, together with, on the market surveillance side, a strengthened responsible-operator obligation, wider obligations for providers of online marketplaces, enhanced EU level IT tools and testing capacity, new EU-level powers including evaluation and monitoring and direct investigation and enforcement, as well as strengthened coordination mechanisms.

- **Regulatory fitness and simplification**

The initiative has a clear REFIT and simplification dimension. Merging Decision 768/2008 on a common framework for the marketing of products, Regulation 765/2008 on accreditation, and Regulation (EU) 2019/1020 on market surveillance, and into a single European Product Act reduces fragmentation, duplication and legal ambiguity across the 29 sectoral acts that currently rely on the New Legislative Framework and the Market Surveillance Regulation, and improves

the readability and consistency of the horizontal rules. Digitalisation of compliance information through the Digital Product Passport is expected to generate document-request and customs-check time savings, while an enhanced, interoperable EU level IT tools and the empowerment of customs authorities to act on formal and obvious non-compliance are expected to bring substantial efficiency gains. Under the 'one in, one out' approach, the package combines burden-increasing and burden-reducing elements: it introduces no new administrative burden for EU economic operators. However, the upgrade of EU level IT tools entails both one-off and recurrent costs for the Commission and the Member States, offset by annual reporting-time savings once interoperability with national systems is achieved.

- **Fundamental rights**

This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, in particular consumer protection, the freedom to conduct a business, the right to be heard, the freedom of expression and information, the right to property and the protection of personal data, and should be interpreted and applied accordingly (see recital 159). Personal data processed under the Regulation, including in the context of the Digital Product Passport and the exercise of market surveillance and enforcement powers, is processed in accordance with Union data protection law, in particular Regulation (EU) 2016/679 and Regulation (EU) 2018/1725, and limited to what is necessary for those purposes.

The impact assessment identifies a relevant fundamental-rights dimension linked to the digitalisation of compliance information, which is intended to support consumer protection under Article 38 of the Charter by improving access to reliable product information and reducing the risk of misleading compliance claims, and to strengthen the effectiveness of market surveillance and enforcement; the policy options concerning cooperation and procedural arrangements between market surveillance authorities were assessed as having no impact on fundamental rights.

4. BUDGETARY IMPLICATIONS

The proposal is estimated to require total commitment appropriations of EUR 472.6 million over the 2028-2034 period under Headings 1 to 4 of the multiannual financial framework, including EUR 136.4 million in digital and IT expenditure supporting infrastructure such as the Digital Product Passport and EU Market Surveillance Data Hub. The implementation of the Regulation is estimated to require additional staffing rising from 71 Full-Time Equivalents in the first year to a steady state of 126 FTEs, covering technical and operational support for digital infrastructure, the technical and legal expertise required to exercise the new EU-level enforcement and evaluation powers, and coordination of EU level activities with Member States; part of this need is expected to be met through redeployment within the Commission, with the remainder requiring additional financing.

The proposal has an impact on revenue: customs authorities will collect a Union market surveillance fee on products entering the Union market, set at a fixed amount per item and calibrated to cover the estimated EU-level costs under the Regulation, with a reduced amount for goods not sold in distance sales; the fee constitutes own resources and is intended to limit recourse to the Union budget for the most resource-intensive tasks. The amount of the Union market surveillance fee shall be set out by an implementing act, following the adoption of the Regulation.

Estimated impacts and staffing for 2028 and beyond are indicative and without prejudice to the outcome of the negotiations on the 2028-2034 multiannual financial framework. Further detail is set out in the Legislative Financial and Digital Statement accompanying this proposal.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission will monitor the implementation, outputs, results and impacts of the EPA from the outset, in cooperation with Member States, market surveillance authorities, customs authorities and, where relevant, notifying authorities, accreditation bodies and notified bodies, relying as far as possible on existing administrative sources such as ICSMS (to become the Market Surveillance Data Hub), Safety Gate and customs data to limit additional burden. Monitoring will draw on the detailed frameworks set out in the accompanying impact assessments, covering monitoring indicators.

In line with Article 151 of the Regulation, the Commission will carry out a full evaluation and report to the European Parliament, the Council and the European Economic and Social Committee every five years, and no earlier than five years after the date of application of the main substantive provisions of the EPA and of the omnibus amendments aligning sectoral legislation, so that sufficient evidence is available on implementation, stakeholder adaptation and impacts.

- **Detailed explanation of the specific provisions of the proposal**

Title I, Chapter 1 (Scope and general principles) sets out the subject matter and material and personal scope, establishing core rules for placing products on the market and making them available. It lays down the requirements to ensure a high level of protection of public interests, such as the protection of health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment, security, and other public interests protected by Union product legislation. It detailly regulates the presumption of conformity based on harmonised standards published in the Official Journal of the European Union, EU harmonisation deliverables, and common specifications adopted by the Commission. Crucially, it sets out the general rules governing the responsible economic operator established in the Union, ensuring that no product is placed on the market unless an operator within the Union territory identified to fulfil statutory compliance tasks.

Title II, Chapter 1 (Obligations of responsible economic operators under the non-aligned Union product legislation) defines the duties of responsible economic operators for non-aligned legislation. It establishes specific obligations to verify the drawing up of the product conformity and the technical documentation, and to keep them at the disposal of market surveillance authorities for the period specified in the applicable law. It introduces detailed requirements regarding the creation, structural content, digital availability, and continuous maintenance of the product responsibility record, ensuring full administrative traceability for non-aligned products.

Title II, Chapter 2 (Obligations of economic operators under the aligned Union product legislation) sets out the complete and harmonised chain of obligations for economic operators under Part I of Annex I. For manufacturers, it dictates the mandatory execution of conformity assessment procedures, drafting of technical documentation, ensuring serial production compliance, carrying out sample testing, handling complaints, applying clear identification markings and creating the digital product passport. For importers, it details the verification of manufacturer compliance, prohibition of placing non-compliant products on the market, transport/storage conditions, and required contact details. For authorised representatives, it specifies the same obligations than for importers and in addition it requires a professional liability insurance to prevent the lack of capacity to fulfil their obligations. For distributors, it specifies pre-market verification duties. For fulfilment service providers, it regulates active cooperation with authorities and handling of compliance documentation. For refurbishers, it

details the obligations when a product that is placed on the Union is modified. Furthermore, it lays down the specific rules for those economic operators regarding the digital product passport and the rules on affixing the physical and digital CE marking, its visual identity, scale, legibility, and presentation alongside digital identifiers.

Title II, Chapter 3 (Obligations of providers of online marketplaces and of economic operators using an online interface) establishes comprehensive e-commerce due diligence rules. Providers of online marketplaces but also the economic operators that at the same time use online interface must design and organize their online interfaces to allow economic operators to display mandatory information, including the CE marking, safety warnings, and access to the Digital Product Passport prior to purchase. It requires online marketplaces to verify the validity of the digital product passport or the product responsibility record of the products to be offered, remove the offers of the products from their platforms under certain conditions and prevent their reappearance, develop a software to fulfil their obligations and become liable for the product compliance in case of not respecting their obligations. Also, it requires to register with the EU market surveillance data hub and provide a single contact point to cooperate with the market surveillance authorities.

Title III, Chapter 1 (Conformity assessment of the products within the scope of the aligned Union product legislation) specifies the precise horizontal framework for conformity assessment procedures. It details the application of modular conformity assessment procedures (Modules A through H), specifying requirements for internal production control, EU-type examination, conformity to type based on internal production control, quality assurance of the production process, product verification, and full quality assurance.

Title III, Chapter 2 (Notification and monitoring of notified bodies) regulates the state designation and oversight of notified bodies. It sets explicit obligations for notifying authorities, details the notification procedure to the Commission and other Member States via the NANDO database, mandates formal identification numbers and lists, structures continuous monitoring and periodic reassessments, and details strict procedures for challenging the competence of notified bodies and handling notifications in cases of suspension, restriction, or withdrawal.

Title III, Chapter 3 (Organisational structure of notified bodies) imposes strict requirements regarding the operational independence and technical capabilities of notified bodies. It mandates legal personality, absolute independence from the assessed entity, and complete impartiality. It explicitly prohibits notified bodies, their top-level management, and assessment personnel from acting as designers, manufacturers, suppliers, installers, purchasers, owners, users, or maintainers of the products they assess, or providing consultancy services. It establishes rules on technical competence, facilities, adequate financial liability insurance, professional secrecy, and sets strict conditions and limitations regarding the subcontracting of tasks or reliance on subsidiaries.

Title III, Chapter 4 (General principles for carrying out conformity assessment by notified bodies) defines how notified bodies perform assessments. It regulates the operational principles, ensuring proportionality without creating unnecessary burdens. It sets out precise requirements for personnel authorization and competence, details the legal admissibility and technical safeguards for remote techniques and virtual audits, mandates thorough documentation and certificates of conformity, establishes transparency and operational duties, and governs information obligations towards notifying authorities, other bodies, and the coordination of notified bodies.

Title III, Chapter 5 (Accreditation) governs the national and European accreditation infrastructure. It sets out principles for national accreditation bodies, mandating a single, non-profit, independent body per Member State operating under public authority. It regulates cross-

border accreditation, strict non-competition principles, information obligations, and peer evaluations administered by the European accreditation infrastructure and defining its official status and legal recognition.

Title IV, Chapter 1 (Digital product passport) lays down a comprehensive horizontal regime for the Digital Product Passport (DPP) that apply to products subject to the relevant Union harmonisation legislation or Union law. It details its operational scope, functional lifecycle, and structural content, including unique product, facility, and operator identifiers, material traceability, environmental footprints, technical documentation, and safety instruction access. It mandates visual data carriers (e.g., 2D barcodes, RFID), defines tiered access rights for the public, authorities, custom officials, repairers, and recyclers, regulates post-market dynamic updates, sets strict data retention schedules, enforces technical design principles based on open, interoperable standards, specifies backup and fallback requirements, details service provider obligations, establishes reference and pre-manufacture DPPs, provides targeted assistance for small and medium-sized enterprises (SMEs), and governs transitional arrangements.

Title IV, Chapter 2 (Storing identifiers and other information in the European Product Act Registry) institutes the European Product Act Registry. It outlines the operational framework managed by the Commission to store unique registration identifiers of products requiring a DPP, along with essential compliance data. Additionally, it establishes product responsibility identifiers for non-DPP items, ensuring seamless validation by customs and surveillance systems.

Title V, Chapter 1 (Market surveillance at Member State level) defines the obligations for national enforcement. Member States must designate market surveillance authorities (MSAs) and a single liaison office, providing necessary resources and legal powers. It details MSA tasks, including regular risk-based inspections, testing, auditing, and specialized DPP verification. It mandates national market surveillance strategies, public information, collaborative activities, joint actions, cost recovery powers, formal enforcement measures, procedural rights, and step-by-step procedures for handling products presenting a risk to health, safety, or public interests, compliant products presenting a risk, formal non-compliance, and mutual assistance mechanisms.

Title V, Chapter 2 (Coordination and cooperation in market surveillance) formally establishes the Union Product Compliance Network to structure joint enforcement across the single market. It sets out the composition, role, and administrative support tasks of the Network and the Commission, structures sector-specific Administrative Cooperation groups (ADCOs), establishes international cooperation protocols, designates Union testing facilities, mandates national DPP coordinators, and sets up the Digital Product Passport Coordination Group.

Title V, Chapter 3 (Market surveillance at Union level) establishes direct intervention mechanisms on market surveillance for the European Commission in restricted cases. It gives the Commission authority to monitor, evaluate, perform direct investigations, and execute direct enforcement interventions when systemic compliance failures threaten the single market. It details procedures for Commission notifications to Member States, centralized coordination, the framework for a Union market surveillance fee to support specialized oversight, and the direct empowerment of the European Union Customs Authority.

Title V, Chapter 4 (Market surveillance on products entering the Union market) regulates border controls and customs procedures. It dictates controls on products entering the Union market, establishing systematic communication channels between customs authorities and MSAs. It mandates the automated verification of the Digital Product Passport and Product Responsibility Record before release for free circulation, details suspension protocols, rules for refusal of

release, procedures for removing online content referring to dangerous or non-compliant imported products, and technical cooperation platforms.

Title V, Chapter 5 (Digital tools for market surveillance) modernizes enforcement technologies. It details the deployment of automated digital and artificial intelligence tools, web-crawlers, and automated software to detect online non-compliance. It regulates the EU Market Surveillance Data Hub, defining its architecture for collecting, processing, and analysing real-time compliance data, inspection reports, and safety alerts across Member States.

Title VI, Chapter 1 (Financial provisions) regulates Union financial assistance for product compliance, accreditation, and market surveillance operations. It lists eligible bodies and activities—including joint actions, testing facilities, standardisation, and digital systems—and details execution methods, administrative conditions, financial interest protections, and budget allocations.

Title VI, Chapter 2 (Delegated powers and committee procedures) sets out the exact conditions for the exercise of delegated powers conferred on the Commission pursuant to the Regulation. It defines the duration, revocation, and objection protocols for delegated acts, and specifies the committee procedures governing implementing measures.

Title VI, Chapter 3 (Confidentiality) provides strict rules regarding the protection of information obtained during the application of the Regulation. It details rules safeguarding commercial confidentiality, trade secrets, intellectual property rights, personal data processing, and security interests, while specifying exceptions for necessary safety disclosures.

Title VI, Chapter 4 (Penalties) mandates that Member States lay down rules on penalties applicable to infringements of the Regulation, taking all necessary measures to ensure they are implemented. It requires penalties to be effective, proportionate, and dissuasive. It introduces rules on direct Union-level administrative fines, establishes strict limitation periods for the imposition and enforcement of penalties, and guarantees fundamental procedural safeguards, including the right to be heard.

Title VI, Chapter 5 (Amendments) details consequential legal amendments to other legal acts. It formally amends the Ecodesign for Sustainable Products Regulation, the General Product Safety Regulation, and the Regulation establishing the Union Customs Code and European Union Customs Authority to harmonise cross-references and operational integration.

Title VI, Chapter 6 (Final provisions) formally repeals legacy acts, explicitly repealing Decision No 768/2008/EC, Regulation (EC) No 765/2008, and Regulation (EU) 2019/1020, establishing that references to repealed acts shall be construed as references to this Regulation. It provides transitional provisions for products, certificates, and notified bodies, dictates periodic evaluation and review reporting requirements for the Commission, and sets the rules for entry into force and deferred date of application.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a framework for product compliance, accreditation, and market surveillance and repealing Decision No 768/2008/EC, Regulation (EC) No 765/2008 and Regulation (EU) 2019/1020

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 33 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[(2)],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The free movement of products constitutes a fundamental pillar of the internal market. Products should circulate freely within the internal market while ensuring a high level of protection of public interests, such as health and safety, including at the workplace, consumer protection, protection of the environment, security and other public interests protected by Union harmonisation legislation. Divergent rules or practices concerning the placing or making available of products on the market, the obligations of economic operators, conformity assessment, notified bodies, accreditation, conformity marking, product information and market surveillance may create obstacles to the free movement of products, distort conditions of competition and undermine the effective and uniform enforcement of Union harmonisation rules.

(2) In order to guarantee the free movement of products within the Union, it is necessary to ensure that products are compliant with Union harmonisation legislation. Robust enforcement of these requirements is essential to the proper protection of these interests and to create the conditions in which fair competition in the Union market for goods can thrive. Rules are therefore necessary to ensure this enforcement, regardless of whether products are placed on the market via offline or online means and regardless of whether they are manufactured in the Union or not.

(3) Strengthening the single market for goods through further enhancing efforts to keep non-compliant products from being placed and circulating on the Union market has been identified as a priority in the Communication from the Commission of 21 May 2025 entitled ‘The Single Market: our European home market in an uncertain world. A Strategy for making the Single Market simple, seamless and strong’. This should be

(1) OJ C [...], [...], p. [...]
(2) OJ C [...], [...], p. [...]

achieved by strengthening market surveillance, providing economic operators with clear, transparent and comprehensive rules, intensifying compliance controls and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities.

(4) The New Legislative Framework adopted in 2008 aimed to improve the internal market for goods while ensuring a high level of protection of public interests, in particular to strengthen the quality of conformity assessment and accreditation, clarify the meaning and credibility of the CE marking, improve market surveillance and provide common principles and reference provisions capable of ensuring greater consistency across the Union for the marketing of products.

(5) Regulation (EC) No 765/2008 established a horizontal framework for accreditation, market surveillance and controls on products entering the Union market and laid down the general principles governing the CE marking to ensure that products covered by Union harmonisation legislation fulfilled requirements providing a high level of protection of public interests while guaranteeing the functioning of the internal market. Its rules on market surveillance and on controls of products entering the Union market were subsequently deleted and replaced by Regulation (EU) 2019/1020.

(6) Decision No 768/2008/EC laid down common principles and reference provisions intended to apply across sectoral Union product legislation in order to provide a coherent basis for the revision or recast of that legislation. It provided, in particular, common definitions, obligations of economic operators, conformity assessment procedures, rules on CE marking, requirements for notified conformity assessment bodies and notifying authorities, notification procedures and procedures for products presenting a risk. Sectoral Union product legislation drew on these common principles and relevant reference provisions, allowing for departures justified by the specificities of the sector concerned.

(7) Since the adoption of the New Legislative Framework, products, manufacturing processes and value chains have changed significantly, driven in particular by digitalisation, connected products, new business models, and the transition towards a circular economy. While the New Legislative Framework remained broadly capable of responding to current and emerging needs, its evaluation found that some provisions risked lagging behind these developments. It therefore identified the need to update the framework to address complex value chains, facilitate remanufacturing and high-quality recycling, and provide common solutions for the digitalisation of product information, including a digital product passport and digital CE marking. A further structural weakness stems from the design of Decision No 768/2008/EC that has produced more than 1 000 Articles and annexes carrying the same or similar wording across sectorial legislation relying on it. Rather than applying directly and uniformly across sectors, it provided only a reference template of common provisions, to be individually transposed into each piece of sectoral Union product legislation. Each transposition allowed for sectorial adaptations, so that, over time, sectoral rules drifted apart both from one another and from the horizontal model they were meant to implement, undermining the very consistency with the horizontal framework that the Decision was designed to ensure.

(8) In order to preserve the coherence achieved by the New Legislative Framework, strengthen the uniform enforcement of the sectorial Union product rules and adapt the horizontal framework to current and future needs, those common rules should be consolidated and updated in a single directly applicable Regulation. Bringing these

common rules together should simplify the Union product rules by facilitating the consistent interpretation and application and by reducing the unnecessary duplication and divergences in sectoral legislation. Furthermore, it will strengthen cooperation between the authorities responsible for the enforcement of Union harmonisation legislation. A single horizontal Regulation should also provide a solid legal basis for a common digital infrastructure and tools supporting product compliance and enforcement.

(9) This Regulation, therefore establishes the European Product Act as the common horizontal framework for products subject to Union harmonisation legislation. It repeals and consolidates the relevant rules currently laid down in 31 sectorial legal acts, and updates them where necessary. This Regulation therefore constitutes a general framework of a horizontal nature for existing and future legislation harmonising the conditions for the marketing of products. The application of the provisions related to the marketing of products continue to apply only to a limited category of products that are listed in Part I of Annex I. The provisions related to the enforcement rules apply to a broader category of products in respect to the scope of this Regulation.

(10) This Regulation also establishes the horizontal framework for the Digital Product Passport that serves as a digital tool for compliance and enforcement purposes applicable to a broad group of products and lays down specific requirements for the Digital Product Passport for the categories of products.

(11) Regulation (EU) 2019/1020 on market surveillance and compliance of products was adopted in 2019, with the objective to strengthen the functioning of the internal market by ensuring effective market surveillance of products covered by the Union harmonisation legislation. It aims at ensuring that only compliant products meeting requirements that protect public interests are made available on the EU market. The Market Surveillance Regulation pursued this objective by establishing rules on the organisation of market surveillance and enforcement of Union harmonisation legislation. It defined the powers and responsibilities of MSAs, set out the cooperation mechanisms between MSAs and customs authorities for imported products, and clarified the obligations of economic operators (EOs) involved in the supply chain. Regulation (EU) 2019/1020 replaced the market surveillance provisions of Regulation (EC) No 765/2008 as of 16 July 2021.

(12) Considering that non-compliant and unsafe products continue to enter and circulate in the Single Market at a large and persistent scale, notably in light of a rapid expansion of e-commerce sales, the market surveillance framework requires improvements to adjust to the new developments. The Market Surveillance Regulation has strengthened the EU market surveillance framework but has only partially achieved its overall objective. It has reinforced the regulatory framework, improved national and EU level cooperation and, to a limited extent, improved enforcement capacity. Nevertheless, significant weaknesses remain in ensuring that non-compliant products, particularly those sold online or imported directly from third countries, are effectively identified and removed from the Single Market.

(13) The framework for market surveillance established by this Regulation should complement existing provisions in Union harmonisation legislation relating to the ensuring of compliance of products and controls on those products entering the Union market. However, in accordance with the principle of lex specialis, the provisions on market surveillance should apply only in so far as there are no specific provisions with the same objective, nature or effect in Union harmonisation legislation. The

corresponding provisions of this Regulation should therefore not apply in the areas covered by such specific provisions.

(14) Regulation (EU) 2023/988 of the European Parliament and of the Council lays down the general safety requirements for all consumer products and provides for specific obligations and powers of the Member States in relation to dangerous products as well as for the exchange of information to that effect through the Safety Gate Rapid Alert System. Market surveillance authorities should have the possibility of taking the more specific measures available to them under that Regulation. In order to achieve a higher level of safety for consumer products, the mechanisms for exchanges of information and rapid intervention situations provided for in Regulation (EU) 2023/988 should be made more effective.

(15) Union harmonisation legislation covers a large share of manufactured products. Non-compliant and unsafe products put citizens at risk and might distort competition with economic operators selling compliant products within the Union.

(16) This Regulation distinguishes between different categories of Union product legislation covered by its scope. For the purposes of this Regulation, Union harmonisation legislation should mean all Union legislation listed in Part I of Annex I. Within that, it is necessary to distinguish between aligned Union product legislation listed in Part I, Title I of Annex I that is based on a common horizontal framework structured around the same governing principles and legal mechanisms concerning the main legal concepts used, and non-aligned Union product legislation, namely the legal acts listed in Part I, Title II of Annex I that do not apply, or do not fully apply, that common horizontal framework.

(17) The provisions on market surveillance of this Regulation should cover products that are subject to the Union harmonisation legislation concerning manufactured products other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level and will help to increase the confidence of consumers and other end users in products placed on the Union market. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to specify whether this Regulation is also to apply to that legislation. In addition, certain provisions on market surveillance of this Regulation apply to non-harmonised products covered under the General Product Safety Regulation as appropriate.

(18) Certain definitions set out in this Regulation should be aligned with definitions set out in other Union legal acts and, where appropriate, reflect the architecture of modern supply chains. The definition of manufacturer in this Regulation should not relieve manufacturers of any obligations they might have under Union harmonisation legislation where specific definitions of manufacturer are applied, which might cover any natural or legal person who modifies a product already placed on the market in such a way that compliance with the applicable Union harmonisation legislation might be affected and places it on the market, or any other natural or legal person who places a product on the market under its name or trademark.

(19) For the purposes of this Regulation, the definitions of economic operators, including that of importer, and the obligations attaching thereto are specific to this legal act. Those definitions and obligations should therefore be interpreted and applied independently of corresponding terms or duties laid down in other Union law, unless otherwise expressly provided.

(20) In order to avoid the reappearance of fragmentation and duplication of the same obligations, sectorial Union product legislation should refer to this Regulation rather than reproduce its horizontal provisions. The aligned Union product legislation should determine the applicable essential or other substantive product requirements, the applicable conformity assessment procedures among those established under this Regulation, and any product-specific information to be included in the digital product passport. However, aligned Union product legislation may include any additions to or derogations from the common framework that are necessary in view of the specific characteristics or risks of the products concerned. Such additions or derogations should be expressly provided for and duly justified. Union law requiring a digital product passport for products should not undermine the integrity or interoperability of the digital product passport by means of sector-specific provisions and should implement any additional substantive requirements exclusively through the common system established in this Regulation.

(21) Whenever legislation is drawn up which concerns a product already subject to other Union acts, those acts must be taken into account to ensure the consistency of all legislation concerning the same product. However, the specificities of sectoral needs may provide grounds for recourse to other regulatory solutions. In particular, that is the case where there are specific, comprehensive legal systems already in place in a sector, as for example in the fields of cosmetic and tobacco products, or where sectoral needs require specific adaptation of the common principles and reference provisions, as for example in the fields of medical devices or construction products. Such adaptations may also be related to the conformity assessment modules established in this Regulation.

(22) The transition towards a more circular economy requires the aligned Union product legislation to accommodate the refurbishment, substantial modifications and other operations intended to extend the useful life of products, while ensuring that products continue to comply with the applicable Union requirements and preventing such operations from being used to circumvent those requirements. This Regulation should therefore establish common rules concerning products that have already been placed on the Union market and are subsequently refurbished or substantially modified.

(23) Where an operation results in a substantial modification of a product, the person responsible for that substantial modification should assume the obligations of the manufacturer in accordance with this Regulation and the applicable aligned Union product legislation.

(24) Refurbishment is not equally relevant or appropriate for all types of products or product sectors. The provisions of this Regulation concerning refurbishment should therefore constitute a common horizontal framework that applies only to products or categories of products for which the applicable aligned Union product legislation expressly provides for its application. In determining whether those provisions should be taken up by the sectorial aligned Union product legislation, account should be taken of the nature and intended purpose of the products concerned, the risks associated with refurbishment, the feasibility of demonstrating continued or reinstated compliance and any existing sector-specific rules. However, the introduction of rules on the refurbishment does not aim to establish an obligation on manufacturers or other economic operators to proceed with such refurbishment in relation to all products. While the resource to refurbishment should remain entirely at the discretion of the relevant economic operators, should they opt for conducting such refurbishment, they would be subject to the rules on refurbishment laid down in this Regulation as they are further implemented by the aligned Union product legislation.

(25) Refurbishment can contribute to the circular economy by extending the useful life of products that have already been placed on the Union market and by encouraging products kept unused by consumers or other end users to be given a second life. Products that have previously been placed on the Union market were required to comply with the applicable aligned Union product legislation requirements at the time of their placing on the market. Provided that such products are not substantially modified and that their compliance with the applicable essential or other substantive requirements is preserved or, where necessary, reinstated through a refurbishment, they can be made available on the market without being assessed again against the applicable EU product rules. The refurbisher should be responsible for demonstrating that the refurbishment has not adversely affected the product's compliance with the applicable essential or other substantive requirements or has reinstated such compliance and should declare this accordingly. Conversely, used products imported from third countries that have not previously been placed on the Union market should not benefit from the refurbishment regime laid down in this Regulation, as their compliance with the applicable rules in the Union has not been previously assessed. Such products should comply with the requirements applicable to products made available on the Union market for the first time, applicable at the moment of placing on the market. This is necessary to prevent used imported products from being placed on the Union market without complying with the applicable Union product rules and thereby placing diligent economic operators who have placed on the Union market products fully complying with the applicable rules at a disadvantage. However, the sole origin of a product should not be the exclusive determining factor. Products that were previously placed on the Union market, subsequently exported and then reimported into the Union should not be treated as products that have never been placed on the Union market. The compliance of such reimported products should be assessed by reference to the requirements applicable when they were first placed on the Union market, without prejudice to any requirements applicable to the refurbishment itself. In order to ensure effective market surveillance and accountability, only refurbishment activities occurring in the Union should be eligible to benefit from the rules on refurbishment under this Regulation, as only those products that were previously placed on the Union market qualify for refurbishment.

(26) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this end, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between economic operators and the market surveillance authorities is a key element, allowing immediate intervention and corrective action in relation to the product. It is important that there should be an economic operator established in the Union so that market surveillance authorities have someone to whom requests can be addressed, including requests for information regarding a product's compliance with Union harmonisation legislation, and who can cooperate with market surveillance authorities in making sure that immediate corrective action is taken to remedy instances of non-compliance. Past experience has shown that, although the existing requirement for an economic operator established in the Union has strengthened enforcement, difficulties remain in ensuring effective accountability for products placed on the market, in particular where products from third countries are offered for sale online or otherwise supplied through distance sales channels. In such situations, market surveillance authorities frequently encounter obstacles in identifying a person established in the Union who is able to provide the necessary documentation, cooperate with authorities and take appropriate corrective action. In order to improve compliance, traceability and enforcement, it is therefore appropriate to ensure that, for products

falling within the scope of this Regulation, a clearly identifiable responsible economic operator established in the Union can be designated.

(27) Each product covered by Union harmonisation legislation should only be placed on the Union market if there is an economic operator responsible for it. That responsible economic operator should be based in the Union and assume a set of responsibilities for the compliance-related tasks linked to products made available on the market. Considering their role in the supply chain or, in case of authorised representatives, the contractual relationship arising from the mandate, and their access to the technical, administrative and commercial information necessary for that purpose, manufacturers, importers and authorised representatives are the economic operators best placed to assume those responsibilities.

(28) The tasks entrusted to the responsible economic operator, such as keeping and making available the required documentation, cooperating with market surveillance authorities and contributing to the timely mitigation of risks presented by products, are essential to ensure that non-compliant or unsafe products can be identified and dealt with effectively. In order to reinforce transparency and traceability throughout the supply chain, and to enable competent authorities to identify without delay the operator responsible for compliance tasks in relation to a given product, information on authorised representatives, mandates and product responsibility should be registered in the European Product Act Registry in accordance with this Regulation. The use of unique operator identifiers should further facilitate reliable identification of the operators concerned, including across digital environments and in relation to products supplied from third countries.

(29) In addition, for products covered by aligned Union product legislation, a set of obligations is defined specifically with respect to manufacturers, importers or authorised representatives. These obligations should go beyond the tasks entrusted under this Regulation to the economic operators responsible for products covered by non-aligned Union product legislation.

(30) The obligations of the economic operators with tasks regarding products subject to certain Union harmonisation legislation should be without prejudice to existing obligations and responsibilities of manufacturer, importer and authorised representative under the relevant Union harmonisation legislation.

(31) Changes in the business models, the complexity of value chains and the circular economy require adapting the economic operators and other actors' obligations that are involved in the marketing of products to face the challenges of this new reality that includes the exponential increase of distance sales and the modification of products after having been placed in the Union.

(32) Economic operators throughout the entire supply chain should be expected to act responsibly and in full accordance with the legal requirements applicable when placing or making products available on the market, so as to ensure compliance with the Union harmonisation legislation on products. The manufacturer should retain ultimate responsibility for compliance of the product with requirements of the Union harmonisation legislation.

(33) Where a manufacturer appoints an authorised representative, the mandate should clearly identify the tasks entrusted to that representative to avoid uncertainty regarding the allocation of responsibilities and to prevent gaps in accountability. The use of digital means for such mandates and for related product responsibility information should

facilitate verification by market surveillance authorities, reduce administrative burden and support more effective enforcement, especially in cross-border and online sales contexts.

(34) Contact information of economic operators with tasks regarding products subject to certain Union harmonisation legislation should be indicated with the product in order to facilitate checks throughout the supply chain. Contact information of economic operators with tasks regarding products subject to certain Union harmonisation legislation should be indicated in the Digital Product Passport in order to facilitate checks throughout the supply chain.

(35) The CE marking should be adjusted to reflect the digitalisation of product-compliance information. During a transitional period, manufacturers should fulfil the requirement to affix the CE marking by physically affixing it to the product, while digital affixing in the digital product passport should also be allowed. After the expiry of that transitional period, the requirement to affix the CE marking should be fulfilled by digitally affixing it in the digital product passport. Where the CE marking is digitally affixed, this should take place only after the applicable conformity assessment procedure has been completed, compliance with the applicable requirements has been demonstrated and the required digital compliance information has been entered in the digital product passport. By digitally affixing the marking, the manufacturer should declare that the product complies with the applicable requirements and assume responsibility for its conformity. A CE marking accessible through the data carrier should connect the marking directly with verifiable compliance information, facilitate controls by market-surveillance and customs authorities and reduce the costs and operational constraints associated with physical affixing.

(36) Providers of online marketplaces play a crucial role in the supply chain, allowing economic operators to reach a greater number of consumers, and therefore also in the product safety system. To protect public interests, this Regulation thus should oblige providers of online marketplaces to cooperate effectively with national authorities and contribute to a level playing field for economic operators across the Union.

(37) Providers of online marketplaces should act with due care in relation to the content hosted on their online interfaces that concerns product compliance, in accordance with the specific obligations laid down in this Regulation.

(38) Moreover, for the purposes of effective market surveillance, providers of online marketplaces should register in the European Product Act Registry and indicate, therein, the information concerning their single point of contact for the facilitation of communication of information on product compliance issues. The Commission should ensure that the registration is easy and user-friendly.

(39) Providers of online marketplaces should designate a single point of contact for consumers. That single point of contact should serve as a single window for consumer communications on product compliance issues, which can then be redirected to the proper service unit of an online marketplace. This should not prevent additional points of contact for specific services being made available to consumers.

(40) In order to be able to comply with their obligations under this Regulation, in particular in respect of the timely and effective compliance with the orders of public authorities, the processing of notices of other third parties and cooperation with market surveillance authorities in the context of corrective measures upon request, providers of online

marketplaces should have in place an internal mechanism for handling product compliance-related issues.

(41) Providers of online marketplaces should be required to verify products before accepting their offers on their platforms and remove non-compliant products upon the reception of notifications. The providers of online marketplaces should not carry out an independent assessment to fulfil these obligations since, due to the digital product passport, the product responsibility record, and the registry, they may do so through automated search tools and technologies. As a result, the obligations imposed by this Regulation on providers of online marketplaces should not amount to a general monitoring obligation or a general active fact-finding obligation, or as a general obligation for providers to take proactive measures in relation to illegal content, such as the sale of dangerous and non-compliant products online.

(42) Where online marketplaces enable consumers to conclude distance contracts with traders for products covered by this Regulation, they should act diligently and in a timely manner where they become aware that a product offered on their interface does not comply with the applicable requirements of this Regulation or presents a risk to the health and safety of consumers or other end-users. Moreover, to ensure an effective enforcement of Union harmonisation legislation, there should always be an entity responsible for product compliance established in the EU. To this end, where providers of online marketplaces gain actual knowledge of product non-compliance or are made aware of facts or circumstances from which such non-compliance is apparent, they should fulfil the obligations that this Regulation imposes on authorised representatives, if two conditions are fulfilled. First, if they have not fulfilled the substantive obligations related to verification and removal of products. Second, if no economic operator responsible for those products is established in the EU.

(43) Remote techniques may improve the efficiency and accessibility of conformity assessment, but should be used only where they do not reduce its effectiveness, reliability or level of assurance. Their use should be based on a documented assessment of the suitability of the activity concerned, taking into account the nature and risks of the product, the need for physical inspection or testing, the reliability of the evidence and the security of the technologies used. Notified bodies should retain full responsibility and control and should carry out an on-site assessment whenever sufficient and reliable evidence cannot be obtained remotely.

(44) This Regulation aims to establish clear, and consistent requirements for the conformity assessment across all the sectors of the Union harmonisation legislation. In order to ensure a high level of protection of public interests, to strengthen confidence in the conformity assessment activities, and to secure the uniform application of Union harmonisation legislation, it is necessary to lay down robust rules on the designation, notification, monitoring and control of notified bodies, as well as on the conduct and oversight of conformity assessment procedures.

(45) In order to ensure a high level of protection of public interests while facilitating the free movement of products, the conformity assessment procedures applicable under this Regulation should be selected and applied in sectorial aligned Union product legislation in a manner that is proportionate to the nature of the risks presented by the products concerned and to the complexity of their design and production. It is therefore necessary to provide for criteria guiding the choice and use of conformity assessment modules so as to ensure consistency across Union harmonisation legislation and to guarantee that the procedures applied are effective, predictable and adapted to the level of risk.

(46) To avoid unnecessary administrative burden and improve the efficiency, traceability and accessibility of procedures, the exchange of information and submissions relating to conformity assessment should, where appropriate, be carried out by digital means. The use of electronic tools should contribute to more effective cooperation between economic operators, conformity assessment bodies and competent authorities, while ensuring legal certainty and maintaining the reliability and evidential value of the information submitted.

(47) In order to ensure a uniform application of the essential or other substantive requirements laid down in the aligned Union product legislation and to facilitate the demonstration of compliance, products which are in conformity with harmonised standards, harmonised standardisation deliverables or common specifications or parts thereof, the references of which have been published in the Official Journal of the European Union, should benefit from a presumption of conformity to the extent covered by those harmonised standards, harmonised standardisation deliverables or common specifications. Such presumption should strengthen legal certainty, reduce compliance costs and support a level playing field, without affecting the possibility for market surveillance authorities to verify compliance with the applicable requirements.

(48) Since notified bodies perform tasks the results of which are recognised throughout the Union, Member States should cooperate closely in the assessment and monitoring of such bodies. Greater transparency and the systematic exchange of relevant information between notifying authorities, national accreditation bodies, market surveillance authorities and the Commission are necessary to detect deficiencies at an early stage, ensure a level playing field for notified bodies and reinforce mutual trust in the notification system.

(49) In order to improve the efficiency and reliability of notification procedures, notifications and related exchanges of information should be carried out through the electronic notification tool made available by the Commission, including the New Approach Notified and Designated Organisations information system (NANDO). The use of a common digital system should support completeness, comparability and timely access to information concerning the status, scope and conditions of notifications.

(50) Given the varying risk profiles associated with the activities of notified bodies and the products covered by this Regulation and the aligned Union product legislation the validity and review of notifications should be subject to an approach that allows the intensity and frequency of monitoring to be calibrated on the basis of objective risk-related considerations. Such an approach should enable competent authorities to focus resources where deficiencies would be most likely to affect the reliability of conformity assessment, while ensuring that all notified bodies remain subject to appropriate and regular oversight.

(51) In order to ensure that notified bodies continuously comply with the requirements placed upon them, their respective notifications should be reviewed by the relevant notifying authorities at regular intervals. In order to ensure a level playing field for notified bodies and ensure coherence in the practices of notifying authorities, this regular interval should be harmonised and set at 5 years. Instances which may have given raise to doubts regarding the competence or compliance of a notified body with the requirements placed upon it should be duly taken into account. Thus, under certain conditions, a more stringent level of assessment of the activities of notified bodies may be required, which would justify a shorter period of reassessment set at 2 years. In cases where the respective notifying authority has not limited the validity of a notification to 2 years

despite evidence to that effect, the Commission may relieve the notifying authority of the responsibility to conduct the reassessment if the said notifying authority fails to sufficiently justify its decision. In such scenario, the Commission should conduct the reassessment of the notified body concerned and should take the appropriate decisions regarding the validity and scope of the notification. Any subsequent reassessments of that notified body should be once again conducted by the relevant notifying authority.

(52) In order to safeguard the uniform application of this Regulation and to address situations where doubts arise as to the competence or compliance of a notified body with the requirements placed upon it, the Commission should be able to examine notifications and to request all information necessary for that purpose. Where appropriate, and without prejudice to the responsibilities of the notifying authorities of the Member States, the Commission should also be able to raise objections and facilitate corrective action so as to ensure that only bodies fulfilling the applicable requirements carry out notified activities.

(53) To ensure the continued credibility of the notification system, notified bodies should be subject to effective monitoring and corrective measures where they no longer meet the requirements applicable to them or fail to discharge their obligations properly. Member States should therefore take appropriate measures, including restriction, suspension or withdrawal of notification, and inform the Commission and the other Member States thereof without delay. Where the relevant notifying authority does not take such actions and fails to justify its inaction, the Commission may open an investigation into the alleged non-compliance of the notified body concerned. Such an investigation may lead to the adoption of appropriate and proportionate corrective measures, including restriction, suspension or withdrawal of notification.

(54) In view of the public interest served by conformity assessment carried out by notified bodies, those bodies should be organised and operated in such a way as to guarantee their independence, impartiality and technical competence. They should therefore be constituted and managed so as to avoid conflicts of interest and to ensure that decisions relating to conformity assessment are taken solely on the basis of objective evidence and in accordance with the requirements of this Regulation.

(55) In order to preserve the credibility of conformity assessment activities, notified bodies, their top-level management and the personnel responsible for carrying out assessment tasks should not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products they assess, nor the authorised representative of any such party. They should likewise be free from any commercial, financial or other pressure liable to influence their judgment, particularly pressure arising from consultancy, design, marketing or other services connected with the products subject to assessment.

(56) The technical competence and reliability of notified bodies depend not only on the qualifications of their personnel but also on the adequacy of their internal organisation, procedures and resources. Notified bodies should therefore have at their disposal the necessary staff, equipment, documented procedures and means to perform the tasks for which they are notified and to ensure consistency, quality and traceability in the performance of those tasks.

(57) Where a notified body subcontracts specific tasks or has recourse to a subsidiary, it remains fully responsible for the tasks performed on its behalf. In order to prevent any weakening of safeguards relating to competence, independence and confidentiality, such subcontracting or use of subsidiaries should be permitted only under strict conditions,

subject to appropriate control and transparency, and should not affect the responsibility of the notified body vis-à-vis the notifying authority and economic operators.

(58) To ensure confidence in the activities of notified bodies throughout the Union, those bodies should participate, directly or through designated representatives, in the relevant coordination and standardisation activities and should apply administrative decisions and guidance documents resulting from the work of notified body coordination groups in a consistent manner. Such participation contributes to the coherent interpretation of requirements, the convergence of practices and the equal treatment of economic operators.

(59) In order to safeguard the impartiality, consistency and reliability of conformity assessment activities, it is necessary to lay down clear rules on the use of subcontracting and subsidiaries by notified bodies. Certain tasks that are essential to the exercise of professional judgement in conformity assessment should therefore not be delegated. In particular, notified bodies should retain responsibility for the review and decision-making functions, as well as for other core assessment tasks having a direct impact on the outcome of the conformity assessment procedure.

(60) In order to ensure the effective enforcement of the rules applicable to conformity assessment bodies, subcontracting should only be allowed within the European Union. Additionally, within the context of the performance of their activities in the scope of their notification, notified bodies should be allowed to make recourse to subsidiaries, provided that those subsidiaries are established within the European Union.

(61) Where subcontracting or the use of a subsidiary is permitted, the notified body should retain full responsibility for all activities carried out on its behalf. It is necessary to ensure that the notified body remains competent to assess and monitor the tasks entrusted to subcontractors or subsidiaries and is able to demonstrate effective oversight of those activities at all times. Those arrangements should not result in a circumvention of the requirements applicable to notified bodies.

(62) In order to reduce risks to the quality and credibility of conformity assessment, subcontracting should be subject to clear and proportionate conditions, including prior verification of competence, documented contractual arrangements, and continuous monitoring of performance. Economic operators should be informed where relevant assessment activities are carried out by a subcontractor or subsidiary, without prejudice to the notified body remaining the single entity responsible vis-à-vis the notifying authority and the economic operator.

(63) In order to reflect technological developments and to improve the efficiency of conformity assessment activities, notified bodies should be allowed to use remote assessment techniques, provided that the effectiveness, quality and reliability of the assessment are thereby preserved and a high level of protection of the public interests.

(64) It is necessary to ensure that remote assessment techniques are used under strict safeguards. They should not replace on-site activities where physical presence is indispensable for the proper verification of compliance, in particular for critical tasks requiring direct observation, testing, inspection of facilities or access to controlled processes and environments. The choice of remote techniques should be based on a documented justification, taking into account the nature of the assessment activity, the risk profile of the product and the operator, and the suitability and security of the technology used.

(65) In order to ensure trust in the use of remote assessment techniques, notified bodies should establish and maintain procedures governing their use, including criteria for determining when remote techniques are appropriate, requirements for secure data transmission and storage, safeguards for confidentiality and integrity, and measures to verify that evidence obtained remotely is sufficient and reliable. Notifying authorities and joint assessment teams should be able to examine those procedures during their monitoring activities.

(66) In order to ensure the continuous availability of the competence necessary for carrying out conformity assessment activities, notified bodies should have a sufficient number of permanently employed personnel at their disposal. The reliance on external personnel should not undermine the notified body's independence, continuity of operations, preservation of knowledge or internal capacity to perform and supervise the tasks for which it has been notified.

(67) It is necessary to establish clearer requirements concerning the competence of personnel involved in conformity assessment activities.

(68) In order to preserve the integrity and coherence of conformity assessment decisions, final decisions on certification, restriction, suspension or withdrawal should be taken only by personnel of the notified body who are duly designated for that purpose and who have not been involved in the assessment of the same case in a manner liable to compromise impartiality. External experts may support assessment activities where strictly necessary, but they should not take decisions on their own nor replace the notified body's internal responsibility for professional judgement.

(69) In order to ensure effective financial responsibility and to strengthen confidence in the operation of notified bodies, those bodies should hold adequate liability insurance corresponding to the nature, scope and risk of the activities for which they are notified, unless liability is assumed by the Member State in accordance with national law. That requirement contributes to ensuring that damage arising from deficient performance of conformity assessment activities can be addressed appropriately.

(70) It is necessary to ensure that notified bodies, their personnel, subsidiaries and subcontractors respect the confidentiality of the information obtained in the course of their activities, while allowing for the exchange of information necessary for the purposes of this Regulation. Rules on professional secrecy should apply without prejudice to the obligations of notified bodies to provide information to notifying authorities, market surveillance authorities and the Commission where required for the exercise of their tasks.

(71) In order to enhance traceability, consistency and transparency, notified bodies should maintain complete, accurate and up-to-date documentation concerning their organisation, decision-making processes, personnel competence, subcontracting arrangements, assessment activities and the certificates and other attestations they issue, suspend, restrict or withdraw. Such documentation is necessary to enable effective monitoring by notifying authorities and to support cooperation between competent authorities.

(72) In order to ensure a consistent and reliable assessment of the competence of conformity assessment bodies, accreditation should be the preferred, but not mandatory, means of demonstrating such competence, unless the applicable aligned Union product legislation requires accreditation. Where accreditation concerns conformity assessment activities, it should be based on the applicable harmonised standards, harmonised standardisation

deliverables and common specifications and, where applicable, additional requirements, including those set out in relevant Union product legislation or relevant sectoral schemes. Where accreditation concerns activities other than conformity assessment, use of harmonised standards or other harmonised standardisation deliverables should not be mandatory. This Regulation should not apply to accreditation required exclusively for conformity assessment under the law of, and access to the market of, a third country, including accreditation granted by an accreditation body of that third country pursuant to an international agreement binding on the Union.

(73) In view of past divergences in the application of the rules governing notified bodies, it is necessary to reinforce structured cooperation and coordination between notified bodies, notifying authorities and the Commission. Participation in coordination groups should contribute to the consistent application of technical and procedural requirements, the exchange of experience and best practices, and the timely identification of emerging issues affecting the quality and uniformity of conformity assessment across the Union.

(74) In order to address shortcomings identified in the supervision of notified bodies and to ensure a more uniform level of performance throughout the Union, Union-level oversight should be strengthened. The Commission should be able, together with Member States, to support joint assessments, develop guidance, facilitate peer learning and follow up on recurring or systemic deficiencies. Clearer requirements on documentation, subcontracting, personnel and remote assessment techniques should reduce legal uncertainty, limit non-compliance and contribute to a more effective and credible notification system.

(75) The digital product passport should constitute a common horizontal tool for making available, in a structured and machine-readable form, product information required under Union law. It should support the demonstration and verification of compliance, improve the identification and traceability of products and economic operators, facilitate conformity assessment, market surveillance and controls on products entering the Union market and reduce unnecessary duplication where the same information is required for several purposes under Union law. Common rules concerning the creation, registration, access, updating, storage and continued availability of the digital product passport and its interoperability with relevant Union information systems should therefore be laid down in this Regulation.

(76) In order to ensure legal certainty, uniform application and a consistent understanding throughout the internal market, the designation ‘DPP’ should be established as the common Union designation for the digital product passport.

(77) In order to ensure the effective and coherent application of digital product passport, the rules set out in this Regulation should apply whenever a digital product passport is required pursuant to this Regulation or pursuant to any other Union legislation. This is necessary to establish a common set of rules governing the functioning and use of the digital product passport.

(78) That framework should apply without prejudice to product-specific Union legislation which may set additional, more detailed or stricter requirements for digital product passports or for the information to be contained therein, having regard to the specific characteristics and policy objectives of the sectors concerned. Where such product-specific Union legislation lays down provisions that go beyond or are more specific than those set out in this Regulation, those provisions should prevail to the extent necessary to ensure consistency with the requirements and objectives applicable to the relevant product group.

(79) Since the digital product passport is intended to make relevant product information available throughout the period required under applicable Union law, it is necessary to ensure that the rules governing that passport cover its entire lifecycle. To that end, this Regulation should provide for requirements relating to the creation, registration, making available, accessibility, updating, storage and maintenance of the digital product passport.

(80) To avoid costs for companies and for the public that are disproportionate to the wider benefits, the digital product passport should be specific to the item, batch or product model, depending on, for example, the complexity of the value chain, the size, nature or impacts of the products considered. Where a product is subject, under Union law, to more than one obligation to establish a digital product passport, a single digital product passport should be established at the most granular level required by those obligations. The term 'model' usually refers to a version of a product of which all units share the same technical characteristics relevant for the data requirements and the same model identifier, the term 'batch' usually refers to a subset of a specific model composed of all products produced in a specific manufacturing plant at a specific moment in time and the term 'item' usually refers to a single unit of a model.

(81) To avoid duplication of investment in digitalisation by all actors involved, including manufacturers, market surveillance authorities and customs authorities and other actors, when other Union legislation requires a digital product passport is required, a single digital product passport should be available containing the information required pursuant to this Regulation and the other Union legislation. The digital product passport should be mandated and implemented in a way that would ensure full interoperability of the system.

(82) Union law may allow economic operators and other relevant actors to provide additional data in the digital product passport in the form of optional or voluntary data. For the purpose of the digital product passport, optional data refers to data points defined but not required by the applicable Union legislation which the economic operators responsible for creating the digital product passport may include in the digital product passport. Applicable Union legislation may also allow the economic operators responsible for creating the digital product passport to include *voluntary data*. Voluntary data refers to data points stored in the digital product passport which are neither defined nor required by Union legislation but which the economic responsible for creating the digital product passport may choose to store in the digital product passport. Where economic operators include voluntary data, such data should comply with the relevant requirements of Union law, in particular as regards accuracy, verifiability and the absence of misleading claims, and should not reduce the clarity, accessibility or visibility of mandatory information and optional data presented in the digital product passport.

(83) A coherent framework of responsibilities for economic operators is essential to ensure that digital product passports contain reliable, complete and up-to-date information. To that end, the economic operator creating the digital product passport should be responsible for the compliance of the product under the applicable Union legislation. That responsibility should encompass the accuracy, completeness and continued updating of the information contained in the digital product passport, as well as the conformity of the product with legal requirements. The assumption of such responsibility should be without prejudice to the obligations and liabilities of other economic operators under this Regulation and under other Union legislation, in accordance with their respective roles in the supply chain.

(84) In order to facilitate checks on the product by market surveillance authorities and to allow the actors in the supply chain and end users to access information on the product, the information on the digital product passport should be provided digitally and in a directly accessible manner, through a data carrier affixed to the product, its packaging or the accompanying documentation. Depending on access rights, market surveillance authorities, customs authorities, economic operators and consumers should have immediate access to the relevant information on the product through the data carrier.

(85) Where other information than the elements required for the digital product passport is provided digitally, the different types of information need to be provided separately and clearly distinguished from each other in the single data carrier. This will facilitate the work of market surveillance authorities but also provide clarity to consumers or other end users regarding the different types of information that are available to them in a digital format.

(86) Given that other Union legislation lays down information requirements for products and sets up systems to make information available to economic operators and end users, the Commission should consider linking information requirements of the digital product passport to existing Union databases and tools such as the European Product Registry for Energy Labelling (EPREL) or the database for information on Substances of Concern.

(87) To ensure the effective roll-out of the digital product passport, its technical design, data requirements and operation should comply with a set of essential technical requirements providing the basis for its consistent deployment across sectors. The technical design should ensure that the digital product passport carries data in a secure way, respecting privacy rules. Technical specifications should be established to ensure the effective implementation of those essential technical requirements. For that purpose, economic operators should take into account where relevant, of harmonised standards developed in support of those requirements, *inter alia,* EN 18216, EN 18219, EN 18220, EN 18221, EN 18222 and EN 18223. Compliance with those harmonised standards should give rise to a presumption of conformity with the relevant requirements of this Regulation. In the absence of such harmonised standards, or where those standards are insufficient to ensure the fulfilment of the essential technical requirements in a timely or adequate manner, the Commission should be able to adopt common specifications by means of implementing acts as a fall-back solution. Compliance with common specifications should also give rise to the presumption of conformity.

(88) To avoid costs for companies and for the public that are disproportionate to the wider benefits, the digital product passport should be specific to the item, batch or product model, depending on, *inter alia*, the complexity of the value chain, the size, nature or impacts of the products considered. Where a product is subject, under Union law, to more than one obligation to establish a digital product passport, a single digital product passport should be established at the most granular level required by those obligations. The term ‘model’ usually refers to a version of a product of which all units share the same technical characteristics relevant for the ecodesign requirements and the same model identifier, the term ‘batch’ usually refers to a subset of a specific model composed of all products produced in a specific manufacturing plant at a specific moment in time and the term ‘item’ usually refers to a single unit of a model.

(89) Where a product incorporates one or more components for which a digital product passport is required under Union law, the digital product passport established for that product should enable the identification of, and access to, the digital product passports

established for those components. For that purpose, the digital product passport of the product should include, for each such component, at least the unique product identifier of the corresponding digital product passport and any other relevant data required under applicable Union law. Access rights to those data should be determined by the applicable Union law.

(90) Where the level of granularity applicable to an incorporated component differs from the level of granularity applicable to the product in which that component is incorporated, the digital product passport of the product should contain, or provide access to, the information necessary to establish a reliable link between the product and the relevant component, batch or item, where this is necessary to identify the specific incorporated component.

(91) Where, following a concluded market surveillance investigation, the digital product passport of an incorporated component is found to be non-compliant, the digital product passport of the product incorporating that component should also be considered non-compliant.

(92) In order to ensure traceability, accuracy of the data and compliance throughout a product's life cycle, the digital product passport should be updated and modified to include information on events and modification on the product occurring after it has been placed on the market or put into service, where such information is required by this Regulation or by other Union law.

(93) For this purpose, a distinction should be made between *non-substantial modifications*, for which the existing digital product passport should be updated, and *substantial modifications*, for which a new passport should be registered and linked to the previous one. In order to ensure legal certainty and avoid disproportionate administrative burdens, clear criteria for determining whether a modification is substantial should be established on case-by-case basis, allowing for product-specific adaptation where justified.

(94) To ensure continuity in the management of digital product passports, it is appropriate to allow economic operators responsible for the digital product passport to transfer a registered digital product passport to a verified economic operator or, where applicable, to another verified actor taking over the responsibilities related to that digital product passport. Such transfer should be possible, in particular, in cases of organisational changes, such as mergers, demergers, the sale of all or part of the business, cessation of activities, or other comparable circumstances.

(95) Unique identification of products is a fundamental element as regards enabling traceability across the supply chain. Therefore, the digital product passport should be linked to a unique product identifier. In addition, where appropriate, the digital product passport should be linked to a unique operator identifier and a unique facility identifier which would allow the actors and manufacturing facilities related to that product to be traced. In order to ensure interoperability, the data carrier, the unique operator identifier and the unique facility identifier enabling traceability should be issued in accordance with internationally recognised standards. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend this Regulation by replacing or adding standards in accordance with which the data carrier, the unique operator identifier and the unique facility identifier can be issued, in light of technical or scientific progress. This should ensure that the data contained in the digital product passport can be recorded and transmitted by all the economic operators, as well as guarantee the compatibility of unique identifiers with external components such as

scanning devices. Moreover, the data should be transferable through an open interoperable data exchange network without vendor lock-in.

(96) To ensure access to the digital product passport for the period specified in delegated acts, including after an insolvency, a liquidation or a cessation of activity in the Union, the economic operator creating the digital product passport should make available a back-up copy of the digital product passport through a digital product passport service provider that is an independent third party.

(97) Economic operators should be able, in accordance with Union legislation, to entrust certain tasks related to the creation, processing, storage, maintenance or making available of data in the digital product passport to digital product passport service providers. The use of such service providers should contribute to the efficient operation, accessibility and interoperability of digital product passports across the internal market, including, where necessary, by supporting continuity of service and the portability of data and functionalities between different service providers or other technical solutions. The entrusting of such tasks should not, however, affect the responsibilities of the relevant economic operator under this Regulation, which should remain fully responsible for compliance with the requirements applicable to the digital product passport and for the accuracy, completeness and timely availability of the information to be included therein.

(98) In order to strengthen data sovereignty within the Union and to ensure that responsible economic operators retain effective control over the hosting of the digital product passport, digital product passport service providers should make it possible for those operators to host the digital product passport and, where relevant, its back-up, in data centres located within the Union.

(99) Where products are sold online, end users should be able to see and access the digital product passport easily before buying the product. For that reason, the digital link to the digital product passport should be clearly visible in the offer.

(100) In the case of distance sales, the specific product intended for the end-user is often not identified at the time the offer is made, since the exact item or batch may be assigned only after the purchase has been completed. In such cases, it may not yet be possible to create the digital product passport relating to the product that will ultimately be supplied. To ensure that customers nevertheless receive relevant product information before making their purchasing decision, economic operators should provide, at the time of the offer, access to a reference digital product passport corresponding to the product model or type concerned. That reference digital product passport should be presented in a manner that is easily accessible and user-friendly, Furthermore, it should clearly indicate that it is provisional and provided for information purposes pending the creation of the final digital product passport for the specific product supplied.

(101) In certain cases, products may be offered for sale or put into service on the market before their manufacture or completion has taken place. In such situations, not all information required for the digital product passport may yet be available. In order to ensure transparency for end users, continuity of information throughout the product lifecycle, economic operators should, where a product is offered for sale or put into service before manufacture or completion, provide end users with a pre-manufacture digital product passport containing the information available at that stage and clearly indicating its provisional nature. That pre-manufacture digital product passport should not substitute the digital product passport and should be consistent with it once the product has been manufactured or completed. In the case of distance sales, including sales through online

marketplaces, the pre-manufacture digital product passport should be displayed in a clear and prominent manner as provisional, and online marketplaces should ensure that it does not replace or appear to replace the digital product passport. Providers of online marketplaces and economic operators using online interfaces should also ensure that end users receive access to the digital product passport once the product has been manufactured or completed. In order to ensure traceability and continuity between provisional and final information, the registry should indicate where a registration concerns a pre-manufacture digital product passport and provide a link between that pre-manufacture digital product passport and the digital product passport corresponding to the final product once the latter is available.

(102) Since many products falling within the scope of this Regulation may be placed on the market or put into service by micro, small and medium-sized enterprises (SMEs), the Commission should provide targeted support to facilitate compliance by those enterprises with the obligations relating to digital product passports. To that end, the Commission should develop and make publicly available practical guidance tailored to the specific needs and constraints of SMEs, including simplified procedures, templates and examples of best practice.

(103) For enforcement and monitoring purposes, it is necessary that competent national authorities and the Commission have direct access to a record of all unique identifiers linked to products placed on the market or put into service. To that end, the Commission should set up and manage a European Product Act registry ('the registry') to store such data. Where needed to further facilitate enforcement, the Commission should, where appropriate, specify other data included in the digital product passport that need to be stored in the registry.

(104) To ensure accountability, each economic operator and value chain actor should be identified through a verification process before registering a digital product passport, a reference digital product passport, a pre-manufacture digital product passport, a product responsibility record or updating data related to them.

(105) For products subject to a requirement to have a digital product passport under the aligned product legislation, the economic operator responsible for creating that digital product passport should obtain a unique registration identifier. To obtain such identifier, that economic operator should register in the registry at least the unique product identifiers and the relevant commodity codes of products intended to be placed under the customs procedure 'release for free circulation', as well as any other information required pursuant to this Regulation or other applicable Union legislation.

(106) Registration of the digital product passport in the registry should be carried out by the economic operator at the level of granularity set out in the applicable Union law, namely at model, batch or item level. In order to ensure full functionality of the registry, in particular for competent national authorities and customs authorities, where a digital product passport is created at item level, the corresponding batch and model identifiers should also be registered together with that digital product passport in the registry, provided that batch and model design exist for the product concerned. For products that are unique by nature, including handmade goods, no batch and model identifiers are required. The same rule applies for digital product passports issued at batch level, where a model identifier is required upon registration. In that context, the batch identifier and the model identifier should represent the higher-level grouping of the product concerned. Those identifiers should be issued by the economic operator in order to enable the competent national authorities to trace products belonging to a specific batch

or model registered in the digital product passport registry. Where the same product is subject to several Union rules requiring registration of its digital product passport at different levels of granularity (model, batch or item), the digital product passport should be registered at the most granular of those levels.

(107) Registration should be carried out by using the secure user interface of the registry provided by the Commission. Once the registration of a digital product passport is successfully validated, a unique registration identifier is generated and stored in the registry and automatically to the actor registering the digital product passport using the same service which was used by the actor to upload the digital product passport data.

(108) The registration of a digital product passport in the registry should imply that the economic operator carrying out that registration assumes responsibility for the compliance of that digital product passport with the applicable requirements laid down in this Regulation and in other relevant Union legislation. Such responsibility should cover, as applicable, the completeness, accuracy and reliability of the information contained in the digital product passport, as well as its conformity with the technical and procedural requirements governing its creation, updating and use.

(109) For products for which no digital product passport is required, and where an authorised representative acts as the responsible economic operator in the Union for such a product on behalf of the manufacturer not established in the Union, there must be a unique product responsibility record to ensure transparency and verification of the responsibility allocation between these economic operators. Since no digital product passport exists for those products, the mandate cannot be linked to a passport containing structured product compliance information. Therefore, a separate product responsibility record should be created for such products in the registry. A product responsibility record should be understood as a registry record used to identify the product, the manufacturer, the authorised representative and the mandate, the relevant product identifier, and, where appropriate, photographs or other pictographic elements enabling identification of the product and the commodity code. The product responsibility record should not constitute a digital product passport, should not contain the structured compliance information required for a digital product passport, and should not, in itself, constitute evidence that the product complies with the applicable Union harmonisation legislation.

(110) To gain a product responsibility record, the manufacturer not established in the EU, or its authorised representative, must register in the registry the product identifiers, the model name, commodity code, and information identifying the manufacturer and the authorised representative, including their operator identifiers, as well as photographs of the product, references to the applicable mandate and any other elements necessary for the functioning of the registry and the exercise of market surveillance. The product responsibility record does not constitute evidence that the product complies with the applicable Union harmonisation legislation.

(111) The mandate by which a manufacturer appoints an authorised representative should be generated and stored in the registry only where the minimum information necessary to identify the parties, the products concerned, the explicit consent of the authorised representative, and the temporal effect of the mandate has been registered. The registry should therefore contain, at least, the unique operator identifiers of the manufacturer and the authorised representative, the relevant product identifier, the model name and the effective date, and should also record the mandate identifier, its scope, validity period, any amendments, as well as its suspension or termination.

(112) Registration should be carried out by using the secure user interface of the registry provided by the Commission. Once the registration of a product responsibility record is successfully validated, a unique product responsibility record identifier is generated and stored in the registry and automatically notified to the actor registering the digital product passport using the same service which was used by the actor to upload the digital product passport data.

(113) The registry should operate in compliance with high-level security standards to protect the integrity, confidentiality and availability of its data.

(114) The Commission, in managing the registry in accordance with the corresponding Articles, should ensure that personal data is processed in accordance with the highest data protection standards in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council. The Commission should therefore be considered the registry's 'controller' as defined in Article 3, point (8), of that Regulation. Personal data should be processed only for the purpose of the management and operation of the registry. That information should be protected from unauthorised access, use, or sharing. Those data should only be kept as long as necessary and should be deleted when user accounts are removed or access is revoked. However, if a user's actions in the registry require data retention for auditing or traceability under Union law, those data should be kept accordingly.

(115) Competent national authorities, such as market surveillance authorities, and customs authorities should have access to the registry for the purpose of carrying out their duties based on their access rights specified in relevant Union and national laws in compliance with Union law. In order to guarantee continuity during the transition from the regime established under Regulation (EU) 2024/1781 to that established by this Regulation. And to prevent any legal or operational gap at the date of application of this Regulation, the registry established pursuant to Article 13(1) of Regulation (EU) 2024/1781 should, on a transitional basis and from that date, constitute the registry referred to in Article 81 of this Regulation. That temporary continuity should facilitate the orderly implementation of this Regulation and provide legal certainty for all relevant actors.

(116) For reasons of legal clarity and consistency, the provisions relating to the digital product passport laid down by Regulation (EU) 2024/1781, should be regulated under this Regulation. This transfer should not affect the continued applicability or functioning of the digital product passport. Accordingly, it should remain valid and continue to be utilised without interruption.

(117) In order to ensure legal certainty and a smooth transition to the rules laid down in this Regulation, identifiers, registration identifiers, data carriers, registry entries and digital credentials issued or created before the date of application of this Regulation pursuant to Regulation (EU) 2024/1781 or other relevant Union harmonisation legislation should remain valid after the date of application of this Regulation. And they should continue to produce their legal effects for the purposes for which they were issued.

(118) To avoid unnecessary disruption, digital product passports placed on the market in accordance with the rules applicable at the time of their issuance should remain valid for the relevant period applied to them. The digital product passport must meet the relevant information requirements and are interoperable with the system established under this Regulation.

(119) In order to ensure legal continuity and avoid regulatory gaps, delegated and implementing acts adopted pursuant to Articles 10 to 13 of Regulation (EU) 2024/1781

before the date of application of this Regulation should remain applicable until they are repealed or replaced.

(120) Responsibility for enforcing Union harmonisation legislation should lie primarily with the Member States, and their market surveillance authorities should be required to ensure that the legislation is fully complied with. The Member States should, therefore, establish systematic approaches to ensure effectiveness of market surveillance and other enforcement activities. In this regard, the methodology and criteria for assessing risks should be further harmonised in all Member States in order to ensure a level playing field for all economic operators.

(121) Member States should designate their own market surveillance authorities. This Regulation should not prevent Member States from choosing the competent authorities to carry out the market surveillance tasks. In order to facilitate administrative assistance and cooperation, Member States should also appoint a single liaison office. Single liaison offices should at least represent the coordinated position of the market surveillance authorities and the authorities in charge of the control on products entering the Union market.

(122) Market surveillance should be thorough and effective, to ensure that Union harmonisation legislation on products is applied correctly. Given that controls may represent a burden for economic operators, market surveillance authorities should organise and conduct inspection activities on a risk-based approach, taking the interests of those economic operators into account and limiting the said burden to what is necessary for the performance of efficient and effective controls. Furthermore, market surveillance should be performed with the same level of care by the competent authorities of the Member State irrespective of whether non-compliance of the given product is relevant on the territory of that Member State or is likely to have an impact on the market of another Member State. Uniform conditions for certain inspection activities carried out by the market surveillance authorities where products or categories of products present specific risks or seriously breach the applicable Union harmonisation legislation might be laid down by the Commission.

(123) In order to assist market surveillance authorities to strengthen consistency in their activities related to the application of this Regulation, an effective peer review system should be established for those market surveillance authorities wishing to participate.

(124) Considering substantial synergies with other compliance-related fields, market surveillance authorities should carry out collaborative activities with other authorities, including customs or consumer protection authorities, or organisations representing economic operators or end users. The collaborative action differs from joint actions on market surveillance, with the latter involving only market surveillance authorities. Collaborative actions agreed between market surveillance authorities and organisations representing economic operators or end users should not lead to unfair competition between economic operators and should not affect the objectivity, independence and impartiality of the parties, for instance, by allowing only certain operators, but not their competitors, to influence the agreement on the criteria or testing methodology of the actions, or by treating differently the economic operators involved in one sector.

(125) Joint actions on market surveillance have contributed meaningfully to EU market surveillance and remain a valuable cooperation tool for market surveillance authorities. Market surveillance authorities may thus agree to conduct joint actions with other market surveillance authorities. To ensure consistent enforcement of the actions across the Member States and generate efficiency gains, market surveillance authorities should

adopt upfront a common risk assessment approach and, unless exceptional circumstances prevent it, to require the relevant economic operators to take the same corrective or restrictive measures where the same nature of non-compliance has been established. To match considerable needs for enhanced market surveillance across all sectors, 38 joint actions should be conducted annually, or as many as the number of ADCOs.

(126) Market surveillance authorities, when performing their duties, are confronted with shortcomings in terms of resources, coordination mechanisms, as well as powers with regard to non-compliant products. Such differences lead to fragmented enforcement of Union harmonisation legislation and to market surveillance being more rigorous in some Member States than in others, potentially compromising the level playing field among businesses and creating also potential imbalances in the level of product safety throughout the Union. In order to ensure that the Union harmonisation legislation on products is correctly enforced, market surveillance authorities should have a common set of investigative and enforcement powers, allowing for enhanced cooperation between market surveillance authorities and more effective deterrence for economic operators that willingly infringe Union harmonisation legislation. Those powers should be sufficiently robust to tackle the enforcement challenges of Union harmonisation legislation, along with the challenges of e-commerce and the digital environment and to prevent economic operators from exploiting gaps in the enforcement system by relocating to Member States whose market surveillance authorities are not equipped to tackle unlawful practices. In particular, the powers should ensure that information and evidence can be exchanged between competent authorities so that enforcement can be undertaken equally in all Member States.

(127) In the digital environment in particular, market surveillance authorities should be able to bring non-compliance to an end quickly and effectively, notably where the economic operator selling the product conceals its identity or relocates within the Union or to a third country in order to avoid enforcement. In cases where there is a risk of serious and irreparable harm to end users due to non-compliance, market surveillance authorities should be able to take measures, where duly justified and proportionate and where there are no other means available to prevent or mitigate such harm, including, where necessary, requiring the removal of content from the online interface or the display of a warning. When such a request is not observed, the relevant authority should have the power to require online marketplaces to restrict access to the online interface. These measures should be taken in accordance with the principles laid down in Directive 2000/31/EC.

(128) This Regulation should be without prejudice to the freedom of Member States to choose the enforcement system that they consider to be appropriate. Member States should be free to choose whether their market surveillance authorities can exercise investigation and enforcement directly under their own authority, by recourse to other public authorities or upon application to the competent courts.

(129) Member States should ensure that adequate financial resources are always available for the appropriate staffing and equipping of the market surveillance authorities. Efficient market surveillance is demanding in terms of resources, and stable resources should be provided at a level appropriate to the enforcement needs at any given moment. Member States should have the possibility to supplement public financing by reclaiming from the relevant economic operators the costs incurred when performing market surveillance in relation to products that were found to be non-compliant.

(130) The implementation of this Regulation and the exercise of powers in its application should also comply with other Union and national law, including with applicable procedural safeguards and principles of the fundamental rights. In particular, procedural rights of economic operators arise from the general principles of Union law and the Charter of Fundamental Rights of the European Union. That implementation and that exercise of powers should also be proportionate and adequate in view of the nature and the overall actual or potential harm caused by the infringement. Competent authorities should take all facts and circumstances of the case into account and should choose the most appropriate measures, namely, those which are essential to address the infringement covered by this Regulation. Those measures should be proportionate, effective and dissuasive. Member States should remain free to set out conditions and limits for the exercise of the powers to fulfil duties in national law. Where, for example, in accordance with national law, prior authorisation to enter the premises of natural persons and legal persons is required from the judicial authority of the Member State concerned, the power to enter such premises should be used only after such prior authorisation has been obtained.

(131) Market surveillance authorities should ensure a high level of transparency while performing their activities and should make available to the public any information that they consider to be relevant in order to protect the interests of end users in the Union.

(132) The Union's internal market relies on the uniform application of Union law and on the mutual trust that national measures governing products comply with that law. When a Member State or the Commission has credible indications that a national measure may result in a product being placed on the market in breach of Union law, a swift and transparent safeguard procedure is required to prevent the circulation of non-compliant products. While the principle of mutual trust obliges Member States to recognise each other's regulatory decisions, it must be complemented by a proportionate oversight tool that can be activated when a product bears a genuine risk and urgent action is needed.

(133) Mechanisms for mutual assistance should be established, since it is imperative for the Union market for goods that the market surveillance authorities of the Member States cooperate with each other effectively. Authorities should act in good faith and, as a general principle, accept requests for mutual assistance. With regard to the cases of mutual assistance requests, the single liaison offices should give any support necessary for cooperation between the relevant authorities. Therefore, the requests for mutual assistance should handled through the EU Market Surveillance Data Hub to ensure swift and efficient information sharing to all authorities.

(134) In order to ensure the effective and uniform enforcement of this Regulation, market surveillance authorities should, where necessary for the performance of their tasks, be able to request expertise from the market surveillance authorities of another Member State. Such expertise may take a form of technical support or expert knowledge and may, in particular, concern the applicable Union harmonisation legislation, relevant harmonised standards, other technical specifications, the state of the art, the technical characteristics of the product concerned, or any other technical, scientific or regulatory element relevant to the assessment of compliance or risk. The authorities receiving such requests should provide, without undue delay and within the limits of their competence and available resources, the expertise requested.

(135) The Union's single market can only function effectively where the Union harmonisation legislation is consistently and uniformly applied throughout the Union. The Commission should be therefore able to monitor and evaluate the application of this Regulation by

the Member States and the functioning of the market surveillance systems that they put in place, including by verifying that they have the necessary powers and resources and carry out appropriate checks on an adequate scale. The Commission should work together with Member States to identify issues in market surveillance and devise appropriate solutions.

(136) A growing number of products made available on the Union's single market, in particular those imported from third countries, including through e-commerce, are offered in numerous Member States at the same time. In addition, recent years have seen a substantial rise in both the complexity of global supply chains and technological sophistication of products. This in turn confronts the national market surveillance authorities with additional needs for resources, expertise or legal tools to act quickly and uniformly. Furthermore, there is no mechanism currently foreseeing Union wide market surveillance and enforcement of Union harmonisation legislation in systemic cases of EU wide infringements that are met with underenforcement at national level. Therefore, to ensure the consistent and coordinated implementation of Union law across all Member States, in accordance with the principles of subsidiarity and respect of national competencies, the Commission should be empowered, on its own initiative or on request from a Member State or consumer or business organisation, to conduct direct investigations. The Commission, in close cooperation with national market surveillance authorities shall have specific powers to intervene directly when non-compliant goods from third countries present a Union-wide risk that cannot be tackled adequately at national level, particularly in the fast-growing sphere of e-commerce imports. These enforcement powers shall be limited to the ones set out by this Regulation and exercised only when specific conditions are met. In addition, to ensure that the Member States can be promptly alerted to emerging risks and are able to coordinate a timely and harmonised market surveillance response, the Commission may, where it has become aware that a product presenting a risk may be found on the territory of one or more Member States, notify those Member States and request that they initiate market surveillance activities.

(137) The Commission should be granted powers of coordination to assist and support market surveillance authorities in carrying our collaborative actions, joint actions or coordinated market surveillance under the purview of ADCOs. To this end, the Commission should be able to support the selection of the product sectors and manage the operational and financial coordination.

(138) To cover the increasing costs of ensuring that only compliant goods that fulfil requirements providing a high level of protection of public interests are made available on the Union market, a Union market surveillance fee, applicable in respect of trade with third countries and commensurate to the approximate cost of the services closely connected to the exercise of Union market surveillance powers should be established on products entering the Union market. While Member States continue to be able to authorise their market surveillance authorities to reclaim from the relevant economic operator the totality of the costs of their activities with respect to instances of non-compliance, the Union market surveillance fee should cover, in particular, costs incurred by the market surveillance authorities and by the Union for the activities necessary to exercise the respective powers of market surveillance under this Regulation. While, as a rule, market surveillance is necessary and is performed on domestic and imported product alike, there are extra-costs for doing so on imported products. This is because of additional costs related to the activities aimed at locating and dealing with EU-based economic operators responsible for imported products and because of other costs, including costs entailed by translation of compliance documents. More in general, the

possibility to access the premises of manufacturers established in the EU allows market surveillance authorities to inspect a large share of a product line, for instance one batch, in a single intervention at manufacturer's premise, a warehouse, distribution centre or retailer. This allows market surveillance authorities to verify processes, technical documentation and quality controls at source rather than relying on a sample, which facilitates enforcement when non-compliance is found. The amount of the Union market surveillance fee should correspond to the approximate extra costs incurred by market surveillance authorities and by the Union when performing market surveillance on imported products compared to the costs of performing it on domestic products. Such fee should not cover the costs incurred by customs authorities when performing market surveillance or their other costs related to handling of products entering the Union market. It is also appropriate to set a lower Union market surveillance fee for products imported in bulk or through customs warehouses for distance sales than for goods packed in individual parcels and directly shipped to the consumer. The debtor of the Union market surveillance fee should be the same person as the debtor of the customs debt, which should be the importer or, in case of distant sales, the importer for distance sales as defined in the Regulation xxx Union Customs Code. Where provisions on importers for distance sales do not yet apply, the debtor should be the declarant as defined in the Regulation xxx Union Customs Code. It is appropriate to provide that the first implementing act setting the amount of the handling fee enters into force rapidly so as to allow the practical application of the Union market surveillance fee introduced by this Regulation to respond to the increasing pressure on market surveillance authorities due to the important volume of goods entering the customs territory of the Union from third countries.

(139) The new Union Customs Code lays down a completely revamped and comprehensive framework for the application and enforcement of non-customs sectoral rules applicable to goods. It should be the primary framework for controls on goods and related actions upon its entry into application, which may be complemented by this Regulation. While customs are the primary authorities to carry out these controls on goods at the EU external borders, including as regards product compliance, Member States should be able to designate other authorities in view of their internal organization to enforce product compliance on products entering the Union market. Product compliance controls should be carried out before the release for free circulation of the products but should also be possible at the occasion of other customs procedures to enhance effectiveness and efficiency, notably in view of new trade models.

(140) The new Union Customs Code empowers customs to independently decided on the compliance of a product with Union law and refuse by themselves the release of such products. These powers will enhance the efficiency and effectiveness of product compliance controls, notably in cases of formal or obvious technical non-compliance where there is no need to consult market surveillance authorities to ascertaining their non-compliance. However, where customs cannot come to such a conclusion or where they consider it necessary for any other reason, they should be able to refer the question of compliance to market surveillance authorities. Such referrals should be subject to a clear process, and the exchanges between customs and market surveillance authorities should take place via electronic means between their respective systems.

(141) Cooperation and exchange of information, including risk information, between customs and other authorities, specifically market surveillance authorities as regards product compliance, is paramount to ensure that non-compliant and dangerous products are identified and prevented to be released for free circulation. The new Union Customs

Code lays down a horizontal framework, which should be usefully completed by specific provisions as regards product compliance in view of the new obligations of economic operators under this Regulation, notably in respect of the Digital Product Passport and the Product Responsibility Record. While Article 109 of the new Union Customs Code already requires indicating to customs the responsible economic operator, this Regulation should require customs to also systematically and automatically verify the information on the responsibility for the product in the registry where available before granting the release of the product.

(142) Custom authorities should be empowered to request that online marketplaces, and other economic operators using online interfaces, remove content or display a warning where products are non-compliant or dangerous.

(143) The Commission should draw a yearly report assessing the performance of the controls on the compliance of products entering the Union market.

(144) The Commission should develop and maintain the technical means enabling the cooperation via and the automated exchanges of information between the registry, the EU Market Surveillance Data Hub, the EU Customs Data Hub and other customs systems, as appropriate. The Commission should be empowered to adopt implementing acts defining the implementation arrangements later on.

(145) It is necessary to establish the Network, hosted by the Commission, aimed at structured coordination and cooperation between enforcement authorities of the Member States and the Commission, and at streamlining the practices of market surveillance within the Union that facilitate the implementation of joint enforcement activities by Member States. This administrative support structure should allow the pooling of resources and maintain a communication and information system between Member States and the Commission, thereby helping to strengthen enforcement of Union harmonisation legislation on products and to deter infringements. The involvement of administrative cooperation groups (ADCOs) in the Network should not preclude the involvement of other, similar, groups involved in administrative cooperation. The Commission should provide the necessary administrative and financial support to the Network.

(146) To address a challenge stemming from an increasingly cross-border nature of market surveillance and generate substantial efficiency gains by avoiding duplication of work, administrative cooperation groups (ADCOs) should ensure structured administrative cooperation between market surveillance authorities and carry out coordinated market surveillance on products that may present a risk in at least two Member States. To that end, the groups should be composed of both representatives of the national market surveillance authorities and, if appropriate, representatives of the single liaison offices, and seconded national experts that are employed and put at disposal of ADCOs by the Member States. The seconded national experts, who in their national role investigate products in their territory sold throughout the EU, would be expected to work on those cases as part of a standing EU market surveillance team. ADCOs should collectively decide when and how to act, either proactively by agreeing an investigation plan upfront or reactively, when a cluster member reports intelligence on a non-compliance risk affecting many Member States. ADCOs' investigations would be conducted either collectively by the entire group, with the Commission coordinating where necessary, or by delegating lead responsibility to one or more MSAs acting on ADCO's behalf, subject to constant monitoring by the wider group. ADCOs should use their best endeavours to reach consensus, in order to, upon the completion of an investigation, ensure EU-wide corrective measures.

(147) To ensure the effectiveness and consistency of testing across the Union in the market surveillance framework with regard to specific products or a specific category or group of products or for specific risks related to a category or group of products, the Commission might designate testing facilities of its own or public testing facilities of a Member State as a Union testing facility. All Union testing facilities should be accredited in accordance with this Regulation. Union testing facilities should only provide services to market surveillance authorities, the Commission, the Union Product Compliance Network (the 'Network') other government or intergovernmental entities and private operators. The Union testing facilities cannot be at any time in a situation of professional conflicting interests regarding the products they deal with.

(148) For the purpose of collecting information relating to the enforcement of Union harmonisation legislation on products, Market Surveillance Data Hub should be upgraded and be accessible to the Commission, single liaison offices, customs and market surveillance authorities. Furthermore, an electronic interface should be developed by the Commission to allow effective exchange of information between their national systems to the Market Surveillance Data Hub.

(149) The amount of data to be entered in Market Surveillance Data Hub should be comprehensive enough to support greater efficiency and effectiveness on the side of the authorities, without imposing excessive administrative burden. Thus, considering substantial efficiency gains in terms of reduced reporting burden due to linking the national systems to the Market Surveillance Data Hub, the data entered in Market Surveillance Data Hub should cover compliance checks carried out in their territory, not limited to in-depth checks of compliance. The completeness of the data collected would further strengthen EU enforcement actions, including those under the Digital Service Act. The Commission should be thus empowered to use the data collected with that purpose, with appropriate safeguards on confidentiality.

(150) Substantial synergies arise between Union level tasks in market surveillance and customs. In particular, the European Customs Authority's role in managing customs data and IT tools, risk analysis and coordinated controls at the Union's external borders would directly support EU market surveillance in e-commerce, through a better information flow, a stronger coherence in actions undertaken in the field of customs and market surveillance at EU level, and an earlier identification of EU wide patterns concerning imports of non-compliant or unsafe products and a more effective risk profiling. In turn, Union level coordination powers in market surveillance, strategic management of the Market Surveillance Data Hub, and powers of direct investigation and enforcement would ensure that intelligence gathered by MSAs translates into effective action at the border. Therefore, the European Customs Authority should be entrusted with the performance of all necessary tasks for the implementation of powers and tasks of the Union linked to the power of monitoring and evaluation, power of direct investigation and enforcement, and the power of coordination.

(151) The exchange of information between market surveillance authorities, and the use of evidence and investigation findings should respect the principle of confidentiality. Information should be handled in accordance with applicable national law, in order to ensure that investigations are not compromised and that the reputation of the economic operator is not prejudiced.

(152) Where, for the purposes of this Regulation, it is necessary to process personal data, this should be carried out in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation is subject to Regulation (EU)

2016/679 of the European Parliament and of the Council and Regulation (EU) 2018/1725 of the European Parliament and of the Council, as applicable.

(153) In order to ensure that access to and use of data for the purposes of this Regulation is proportionate and does not impose unnecessary burdens or risks, different categories of data should be treated in a differentiated manner according to their nature and the circumstances in which they are obtained. Data that are publicly available may, by their nature, be subject to the least restrictive conditions. Data that are routinely collected by public authorities in the exercise of their tasks may, depending on the context and the risks involved, be used in aggregated or non-aggregated form. By contrast, data specifically requested from businesses, whether through tailored information requests or in the context of inspections, may entail greater sensitivity, including as regards confidential business information and the administrative burden placed on the undertakings concerned, and therefore justify more restrictive conditions for access and use.

(154) The Commission should be able to exchange market surveillance related information with regulatory authorities of third countries or international organisations within the framework of agreements concluded between the Union and third countries or international organisations, with a view to ensuring compliance of products prior to their export to the Union market.

(155) The Commission should carry out an evaluation of this Regulation in light of the objective it pursues, and taking into consideration new technological, economic, commercial and legal developments. Pursuant to point 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law Making, the evaluation, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action, particularly as regards the scope of this Regulation, the application and enforcement of the provisions related to the tasks of economic operators placing products on the market, and the system of product- related pre-export controls.

(156) The financial interests of the Union should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties.

(157) Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of penalties and periodic penalty payments. To that end, appropriate levels of penalties and periodic penalty payments should also be laid down for non-compliance with the obligations and breach of the procedural rules, subject to appropriate limitation periods in accordance with the principles of proportionality and ne bis in idem. The Commission and the relevant national authorities should coordinate their enforcement efforts in order to ensure that those principles are respected. In particular, the Commission should take into account any fines and penalties imposed on the same legal person for the same facts through a final decision in proceedings relating to an infringement of other Union or national rules, so as to ensure that the overall fines and penalties imposed are proportionate and correspond to the seriousness of the infringements committed. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU. The Court of Justice of the European Union should have unlimited jurisdiction in respect of fines and penalty payments in accordance with Article 261 TFEU.

(158) Where national enforcement measures prove insufficient, the Commission must be empowered to impose Union-level penalties that are effective, proportionate and dissuasive. Such penalties complement Member State sanctions, reinforce compliance across the internal market and ensure that violations of the Regulation are addressed uniformly and swiftly at Union level.

(159) This Regulation respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and present in the constitutional traditions of Member States. Accordingly, this Regulation should be interpreted and applied in accordance with those rights and principles, including those related to the freedom and pluralism of the media, with applicable procedural safeguards and with the Union rules on data protection, in particular Regulation (EU) 2016/679. In particular, this Regulation seeks to ensure full respect for consumer protection, the freedom to conduct a business, the right to be heard, the freedom of expression and information, the right to property and the protection of personal data.

HAVE ADOPTED THIS REGULATION:

TITLE I

GENERAL PROVISIONS

Chapter 1
Scope and general principles

Article 1

Subject Matter

In order to improve the functioning of the internal market by facilitating the free movement of goods into and within the Union and at the same time by ensuring a high level of protection of public interests pursued by this Regulation, in particular the health and safety of persons, including consumers and professional users, as well as the protection of property and domestic animals, the environment and the public security, this Regulation lays down:

(a) common rules related to the design, conformity assessment and manufacture of products subject to the aligned Union product legislation and subject to the Regulation (EU) 2023/988 [GPSR] as specified in Article 2;

(b) a framework for the market surveillance of products be they manufactured in the Union or in a third country, that are subject to the Union harmonisation legislation and subject to the Regulation (EU) 2023/988 [GPSR] as specified in Article 2.

Article 2

Material scope

1. This Regulation shall apply to products subject to the Union harmonisation legislation.

2. Within this Regulation, the scope of application of the different Chapters shall be further defined as follows:

   (a) As regards product compliance:

      i. the following Chapters and Articles of this Regulation shall apply only to products that are subject to the aligned Union product legislation listed in Part I, Title I of Annex I and only where that legislation, or other Union law, expressly provides for their application: Title II, Chapter 2 and Chapter 3; Title III; Title IV, Chapter 1 and Articles 81 and 82 of Chapter 2. Where appropriate in view of the specificities of the sector concerned, the provisions laid down by this Regulation may be further complemented by sector-specific provisions laid down in the aligned Union product legislation;

      ii. the following Chapters and Articles of this Regulation shall apply to products that are subject to the non-aligned Union product legislation listed in Part I, Title II of Annex I: Title II, Chapter 1 and Chapter 3 and, where provided for in that legislation, Title II, Chapter 2, Articles 18 and 19; Title III; Title IV, Chapter 1 and Article 81, Article 82, and Article 83 of Chapter 2.

(b) As regards market surveillance, the following Chapters and Articles shall apply to products that are subject to the Union harmonisation legislation of Part I of Annex I in so far as that legislation does not contain specific provisions governing the matters covered by those Chapters and Articles: Title V, Chapter 1, Articles 105 to Article 111 of Chapter 2, Chapter 3 and Chapter 5.

(c) For products falling withing the scope of Regulation (EU) 2023/988 [GPSR] that are subject to Union product legislation listed in Part II of Annex I, and without prejudice to any specific provision with the same objective in that Regulation, the following Articles shall apply: Title I, Chapter 1, Article 9; Title II, Chapter 1, Article 13 of Chapter 2, paragraphs 7 and 8 of Article 21 of Chapter 3; Title IV; Title V, Chapter 4 and Article 128 of Chapter 5; Title VI, Chapter 4, Article 139 to Article 143. In addition, by virtue of Article 23 of Regulation (EU) 2023/988, the following provisions shall also apply: Title II, Article 15 and Article 16 of Chapter 2, Article 20 and paragraphs 1 to 6 and 9 to 11 of Article 21 of Chapter 3; Title IV, Chapter 2, Article 83; and Title V, Chapter 1, Chapter 3 and Chapter 5.

(d) As regards accreditation, Title III, Chapter 5 shall apply to accreditation of conformity assessment bodies or other natural or legal persons, relating to conformity assessment or other activities, and irrespective of the legal status of the body performing the accreditation;

(e) As regards the Digital Product Passport, Title IV, Chapter 1 and Articles 81 and 82 of Chapter 2; Title V, Articles 112, 113 and 114 of Chapter 2 shall apply to products subject to Union law that provides for the application of the Digital Product Passport;

(f) As regards products entering the Union, Title V, Chapter 4 shall apply to products covered by Union law in so far as there are no specific provisions relating to the carrying out of control on products entering the Union market in Union law.

Article 3

Personal scope

The applicable Articles of this Regulation shall apply to the following natural or legal persons:

(a) economic operators as defined in this Regulation and equivalent economic operators as defined in the aligned Union product legislation;

(b) providers of online marketplaces;

(c) economic operators using an online interface;

(d) other economic operators in Union law;

(e) market surveillance authorities;

(f) Union customs authorities.

Article 4

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) ‘Union harmonisation legislation’ means any Union legislation listed in Part I of Annex I;

(2) ‘aligned Union product legislation’ means the Union harmonisation legislation listed in Part I, Title I, of Annex I;

(3) ‘non-aligned Union product legislation’ means the legal acts of Union harmonisation legislation listed in Part I, Title II, of Annex I;

(4) ‘non-compliance’ means any failure to comply with any requirement under the Union harmonisation legislation or under this Regulation;

(5) ‘making available on the market’ means any supply, by any means, of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(6) ‘placing on the market’ means the first making available of a product on the market in the Union;

(7) ‘putting into service’ means the first use of a product in the Union in the course of a commercial or non-commercial activity, whether in return for payment or free of charge, where that product has not been placed on the market prior to its first use;

(8) ‘formal requirements’ means any requirements which:

(a) provide the compliance information on the product or included in the digital product passport, namely, the product data requirements, digital compliance information, including the relevant economic operators contact details, and the affixed CE marking or any other mandatory conformity marking where provided in under aligned Union product legislation;

(b) make the visual identity of the digital product passport and the data carrier to access the digital product passport clearly visible and accessible;

(c) draw up the required technical documentation.

(9) ‘essential or other substantive requirements’ means legally binding requirements laid down in Union harmonisation legislation in order to ensure the protection of legitimate public interests pursued by that legislation, irrespective of how they are designated and whether they are expressed as objectives, performance requirements, or detailed specifications;

(10) ‘product’ means any tangible or intangible substance or item as determined by the respective provisions governing the material scope of the relevant applicable Union harmonisation legislation, that can lawfully be the object of a transaction, whether interconnected to other substances or items or not, whether supplied or made available for consideration or free of charge.;

(11) ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

(12) ‘responsible economic operator established in the Union’ means any natural or legal person established within the Union who places or is deemed to place a product on the Union market, and which, based on the criteria for designation laid down in this Regulation, may be either the manufacturer if established in the

Union or its authorised representative having received a digital mandate, or in cases where the manufacturer is not established in the Union, an importer or an authorised representative who has received a digital mandate by the manufacturer;

(13) 'authorised representative' means any natural or legal person established within the Union who has received a digital mandate from a manufacturer to act on its behalf in relation to the tasks and obligations specified in Article 13 for the products covered by the aligned Union product legislation or Article 10 for products covered by the non-aligned Union product legislation;

(14) 'importer' means any natural or legal person established within the Union who places a product from a third country on the Union market;

(15) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

(16) 'fulfilment service provider' means a natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, with the exclusion of postal services as defined in Article 2(1) of Directive 97/67/EC of the European Parliament and of the Council, parcel delivery services as defined in Article 2(2) of Regulation (EU) 2018/644 of the European Parliament and of the Council, and any other postal services or freight transport services;

(17) 'refurbisher' means a natural or legal person that carries out actions to prepare, clean, test, service and, where necessary, repair a product or a discarded product that has already been placed on the Union market in order to restore its performance or functionality within the intended use and range of performance originally conceived at the design stage at the time of making the product available on the Union market;

(18) 'provider of an online marketplace' means a provider of an intermediary service using an online interface which allows users to conclude distance contracts with economic operators for the sale of products;

(19) 'economic operators' means the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider, the refurbisher or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonisation legislation, irrespective of the sales channel used;

(20) 'end user' means any natural or legal person residing or established in the Union, to whom a product has been made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of or the purpose of its industrial or professional activities;

(21) 'distance contract' means a distance contract as defined in Article 2(7), of Directive 2011/83/EU;

(22) 'substantial modification' means a non-negligeable modification of a product, by physical or digital means after that product has been placed on the market or put into service, which is not foreseen or planned by the manufacturer, and which affects the safety or other essential or other substantive requirements of that

product, by creating a new risk, or by increasing an existing risk or by having an impact in the performance of the product;

(23) ‘accreditation’ means ‘accreditation’ means an attestation by a national accreditation body that a conformity assessment body, or other natural or legal person, meets the necessary requirements to carry out a conformity assessment or other activity;

(24) ‘sectoral schemes’ means accreditation programs specialised for the conformity assessment of products from specific industrial sectors;

(25) ‘national accreditation body’ means the sole body in a Member State that performs accreditation with authority derived from the State;

(26) ‘conformity assessment’ means the process through which it is verified whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

(27) ‘conformity assessment body’ means a legal or physical person that performs conformity assessment activities including calibration, testing, certification and inspection;

(28) ‘notified body’ means a conformity assessment body which has been notified by the notifying authority of a Member State to perform conformity assessment activities where such conformity assessment is mandatory under Union harmonisation legislation;

(29) ‘New Approach Notified and Designated Organisations Information System‘ (NANDO), means an electronic notification and information system developed and managed by the Commission for the notification of conformity assessment bodies and other organisations in accordance with Union harmonisation legislation, comprising a publicly accessible interface providing information on the scope of notification and the status of notified or designated bodies, and an internal database containing, inter alia, accreditation certificates, the accredited scope, and a dedicated module enabling notified bodies to upload and manage their certificates under each applicable Union harmonisation legislation.

(30) ‘supply chain’ means all upstream and downstream activities and processes of a product’s value chain which are related to its production – including its design, extraction, sourcing, manufacture, transport, storage and supply of raw materials or components, and development – and the activities aiming at its making available on the market including import (as the case may be), transport, storage, distribution and sale, up to the point where the product reaches the end user;

(31) ‘value chain’ means all activities, resources and processes that are part of the life cycle of a product, from conception to delivery, consumption and end-of-life, including its possible substantial modification;

(32) ‘digital product passport’ (‘DPP’) means a structured set of data specific to a product model, batch or item, accessible via electronic means through a data carrier, linked to a persistent unique product identifier and to a unique registration identifier issued by the registry, and containing the information required under Union law;

(33) ‘data carrier’ means a linear barcode symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device in a univocal manner;

(34) ‘unique product identifier’ means a unique string of characters that serves the identification of a single product model, batch or item in a univocal manner and that enables a digital link to the digital product passport;

(35) ‘product identifier’ means a unique alphanumeric code assigned to a product, ensuring its precise and unambiguous identification and its traceability at every stage of the supply chain, from the offering for sale, including online or distance sale, to the sale and supply, and to post-sale market activities;

(36) ‘non-standardised manufacturer product identifier’ means a product identifier that is assigned by a manufacturer or product supplier and which does not rely on internationally recognised standards;

(37) ‘standardised manufacturer product identifier’ means a product identifier that is assigned by a manufacturer, producer or product supplier and which relies on internationally recognised standards;

(38) ‘merchant product identifier’ means a product identifier assigned by an online seller, marketplace or platform;

(39) ‘unique operator identifier’ means a unique string of characters for the identification of an actor involved in a product’s chain;

(40) ‘unique facility identifier’ means a unique string of characters for the identification of locations or buildings involved in a product’s supply chain or used by actors involved in a product’s value chain;

(41) ‘unique registration identifier’ means a unique string of characters automatically communicated by the registry referred to in Article 81 and associated with the unique identifiers uploaded in the registry for a specific product model, batch or item;

(42) ‘digital product passport service provider’ means a natural or legal person that is a third party independent but instructed by the economic operator responsible for the creation and content of a digital product passport or its back-up and that processes the digital product passport data for the purposes of storing those data, making them available to economic operators and other relevant actors endowed with the right to access them under this Regulation or other Union law;

(43) ‘reference digital product passport’ means a set of data made available in relation to an offer for distance sales where the item or batch to be supplied and its associated digital product passport cannot yet be identified, containing the information that can be reliably estimated for the whole model, that is common to all items or batches of the product model concerned;

(44) ‘pre-manufacture digital product passport’ means a set of data made available in relation to an offer for sale of a product that has not yet been manufactured, containing the information relating to that product that can be reliably determined or estimated at the time the offer is made;

(45) ‘product responsibility record’ means an electronic entry registered in the registry for a product that is not subject to an obligation to have a digital product passport, containing the data necessary to identify that product, the manufacturer not established in the Union, the authorised representative established in the Union, and the mandate by which that manufacturer appoints that authorised representative to act on its behalf for that product;

(46) ‘standard’ means a standard as defined in Article 2 of the [the revised Standardisation Regulation];

(47) ‘harmonised standard’ means a harmonised standard as defined in Article 2 of [the revised Standardisation Regulation];

(48) ‘harmonised standardisation deliverable’ means a harmonised standardisation deliverable as defined in Article 2 of [the revised Standardisation Regulation];

(49) ‘common specification’ means a technical specification as defined in Article 2 of [the revised Standardisation Regulation];

(50) ‘safety or other public interest-related information’ means information, including warnings, precautions, limitations, instructions and other information necessary, in view of a product’s intended purpose, intended users and reasonably foreseeable use or misuse, to ensure the protection of safety or of any other public interest covered by the applicable aligned Union product legislation, throughout the installation, use, interaction with and lifecycle of the product, including information on risks or other factors relevant to the protection of such public interests that remain after applicable risk-reduction or other compliance measures have been taken;

(51) ‘essential safety or other public interest-related information’ means the part of the safety or other public interest-related information without which the product cannot be installed, used or otherwise operated in accordance with the applicable requirements intended to protect safety or another public interest covered by the applicable aligned Union product legislation

(52) ‘instructions for use’ means a set of instructions containing:

(a) the description of the intended use of the product also taking into account any reasonably foreseeable misuse there;

(b) drawings, diagrams, descriptions and explanations necessary for the use, maintenance, and repair of the product;

(c) where relevant, information on the adjustment and maintenance operations related to a product, the specifications of the spare parts to be used in/for it;

(53) ‘instructions for refurbishment’ means the non-confidential technical and other information that is made available by the manufacturer, including information on the performance and compatibility of non-proprietary spare parts and other elements necessary for refurbishment and that enables a refurbisher to carry out refurbishment operations without adversely affecting the product’s compliance with the essential or other substantive requirements applicable at the moment the product was placed on the market or, where compliance has been affected, to reinstate such compliance;

(54) ‘digital contact’ means any up-to-date and freely accessible online communication channel, such as an email address through which an economic operator can be contacted without the need for the contacting party to register, download or use additional applications specific to the economic operator;

(55) ‘market surveillance’ means the tasks carried out and measures taken by market surveillance authorities and the Commission to ensure that products comply with the requirements set out in the applicable Union harmonisation law and other

Union legislation to ensure the protection of the public interests pursued by that legislation;

(56) ‘market surveillance authority’ means an authority designated by a Member State pursuant to Article 84(2) as responsible for carrying out market surveillance in the territory of that Member State;

(57) ‘applicant authority’ means the market surveillance authority that makes a request for mutual assistance;

(58) ‘requested authority’ means the market surveillance authority that receives a request for mutual assistance;

(59) ‘online interface’ means any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator or a provider of an online marketplace, and which serves to give end users access to the economic operator’s products;

(60) ‘corrective action’ means any action taken by an economic operator to bring any non-compliance to an end where required by a market surveillance authority;

(61) ‘voluntary measure’ means any action taken by an economic operator to bring any non-compliance to an end where not required by a market surveillance authority;

(62) ‘risk’ means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm;

(63) ‘product presenting a risk’ means a product having the potential to affect adversely the health and safety of persons in general, health and safety in the workplace, protection of consumers, environment, public security and other public interests, protected by the applicable aligned Union product legislation and other Union law, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

(64) ‘product presenting a serious risk’ means a product presenting a risk, for which, based on a risk assessment and taking into account the normal and foreseeable use of the product, the combination of the probability of occurrence of a hazard causing harm and the degree of severity of the harm is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the risk are not immediate;

(65) ‘recall’ means any measure aimed at achieving the return of a product that has already been made available to end users;

(66) ‘withdrawal’ means any measure aimed at preventing a product in the supply chain from being made available on the market;

(67) ‘customs authorities’ means customs authorities as defined in Article 5(1) of Regulation (EU) [nUCC] and, where relevant for carrying out its mission and duties pursuant to Regulation (EU) [nUCC], the EU Customs Authority;

(68) ‘release for free circulation’ means the customs procedure laid down in Article 109 of nUCC];

(69) ‘release’ means‘ release of the goods’ as defined in Article 77 of the Regulation [nUCC];

(70) ‘product entering the Union market’ means a product from a third country intended to be placed under the customs procedure ‘release for free circulation’ and either intended to be placed on the Union market or intended for private use or consumption within the customs territory of the Union.

(71) ‘Union product legislation’ means any Union legislation listed in Annex I;

Article 5

Obligation of compliance for the purposes of placing products on the market

1. Economic operators shall only place on the Union market products that comply with the requirements laid down the applicable Union product legislation, including in this Regulation.

2. For products subject to aligned Union product legislation, the requirements referred to in paragraph 1 shall include the applicable provisions of this Regulation, the formal requirements and the essential or other substantive requirements set out in the applicable aligned Union product legislation.

3. For products subject to non-aligned Union product legislation, the requirements referred to in paragraph 1 shall include the applicable provisions of this Regulation, the requirements laid down in the relevant non-aligned Union product legislation.

4. For products subject to the Regulation (EU) 2023/988 [GPSR], the requirements referred to in paragraph 1 shall include the applicable provisions of this Regulation, the requirements laid down in the Regulation (EU) 2023/988 [GPSR].

5. Economic operators, as defined in the Union product legislation, shall, further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product with this Regulation and the Union product legislation in a language which can be easily understood by that authority.

6. Where the product is required to have a digital product passport, the information and documentation referred to in paragraph 1 shall be provided to the competent national authority through the digital product passport.

7. Products offered through a targeted offer for sale online or through other means of distance sales shall be deemed to be made available on the market if the offer is targeted at end users in the Union. An offer for sale shall be considered to be targeted at end users in the Union if the relevant economic operator directs, by any means, its activities to a Member State.

Article 6

Obligation of cooperation

1. The economic operators referred to in paragraph 1 of Article 5 shall cooperate with competent national authorities, at their request, as regards any action taken to eliminate the risks posed by products in relation to which they carry out activities under this Regulation.

2. Besides the specific cooperation obligations laid down in other Articles of this Regulation, economic operators shall cooperate fully and effectively with market surveillance authorities in the exercise of their powers under this Regulation, upon their request or where necessary in view of the need to ensure compliance for the products it made available on the market or to eliminate or mitigate the risks presented by those products.

3. Fulfilment service providers shall cooperate as regards product withdrawals or recalls, regardless of whether initiated by authorities, the manufacturer, the authorised representative or the importer.

4. Providers of online marketplaces and economic operators using an online interface shall cooperate with the market surveillance authorities, at the request of the market surveillance authorities in the exercise of their powers under this Regulation and in specific cases, to facilitate any action taken to eliminate or, if that is not possible, to mitigate the risks presented by a product that is or was offered for sale online through their services and any other request on formal requirements.

Article 7

Level of protection of public interests

1. The aligned Union product legislation shall restrict itself to setting out the essential or other substantive requirements determining the level of protection of public interests and shall express those requirements in terms of the results to be achieved. Where recourse to essential or other substantive requirements is not possible or not appropriate, in view of the objective of ensuring the adequate protection of public interests, detailed specifications may be set out in the aligned Union product legislation concerned.

Article 8

Presumption of conformity based on harmonised standards, harmonised standardisation deliverables and common specifications

1. Where aligned Union product legislation sets out essential or other substantive requirements, compliance with those requirements may be demonstrated by means of the applicable harmonised standards, harmonised standardisation deliverables or common specifications. For that purpose, those requirements may be expressed in technical terms through harmonised standards, harmonised standardisation deliverables or common specifications. Compliance with such harmonised standards, harmonised standardisation deliverables or common specifications may, alone or in conjunction with others, give rise to a presumption of conformity with the corresponding essential or other substantive requirements, or parts thereof, without precluding compliance with those requirements from being demonstrated by other means.

2. Products which are in conformity with harmonised standards or parts thereof, harmonised standardisation deliverables or parts thereof, or common specifications or parts thereof shall be presumed to be in conformity with the requirements set out in the applicable aligned Union product legislation, insofar as those requirements are covered by the relevant harmonised standard, standardisation deliverable, common specification or part thereof..

3. Digital product passports which are in conformity with harmonised standards or parts thereof, harmonised standardisation deliverables or parts thereof or common specifications or parts thereof shall be presumed to be in conformity with the requirements set out in Chapter 9 of Title II, insofar as those requirements are covered by the relevant harmonised standard, harmonised standardisation deliverable, common specification or part thereof.

4. Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof harmonised standardisation deliverables or parts thereof, or common specifications or parts thereof that correspond to the requirements applicable to conformity assessment bodies under Articles 22 to 49, it shall be presumed to comply with those requirements in so far as the applicable harmonised standards, harmonised standardisation deliverables or common specifications cover those requirements.

5. The presumption of conformity referred to in paragraph 4 shall apply only to the requirements applicable to conformity assessment bodies under Articles 22 to 49 insofar as those requirements are covered by the relevant harmonised standards, harmonised standardisation deliverables or common specifications or part thereof. Where this Regulation or a Union harmonisation legislation lays down requirements for conformity assessment bodies that are more stringent than those covered by such harmonised standards, standardisation deliverables or common specifications, or additional requirements that are not covered by them, the presumption of conformity referred to in the paragraph 4 shall not apply to those more stringent or additional requirements. In such cases the national accreditation body shall directly assess whether the conformity assessment body complies with those requirements before issuing the accreditation certificate.

Article 9

Responsible economic operator established in the Union

1. Without prejudice to any specific provision with the same objective in the applicable non-aligned Union product legislation or in Regulation (EU) 2023/988 [GPSR], a product subject to Union product legislation listed in Annex I may be placed on the market only where there is a responsible economic operator established in the Union in respect of that product.

2. The responsible economic operator established in the Union referred to in paragraph 1 shall be:

   (a) where the manufacturer is established in the Union, that manufacturer; or

   (b) where the manufacturer is not established in the Union:

      i. the importer; or

      ii. an authorised representative who has a digital mandate from that manufacturer to act on its behalf in respect of specific products.

3. Where a manufacturer is not established in the Union designates an authorised representative as the responsible economic operator pursuant to paragraph 2(b)(ii), it shall ensure that, at any given time, only one such authorised representative is designated in respect of each product throughout the Union. The digital mandate shall identify the product or products covered by the designation and the date from which the designation takes effect.

4. This article shall not apply in relation to a product that is subject to Regulation (EC) No 1223/2009, Regulation (EU) No 305/2011, Regulation (EU) 2017/745, Regulation 2017/746 or Regulation 2017/1369.

TITLE II

OBLIGATIONS OF ECONOMIC OPERATORS AND PROVIDERS OF ONLINE MARKETPLACES

Chapter 1
Obligations of responsible economic operators under non-aligned Union product legislation and Regulation (EU) 2023/988 [GPSR]

Article 10

Obligations of the responsible economic operator established in the Union

1. Without prejudice to any obligations of economic operators in the applicable non-aligned Union product legislation and Regulation (EU) 2023/988 [GPSR], the economic operator referred to in Article 9 shall, in respect of products under non-aligned Union product legislation or Regulation (EU) 2023/988 [GPSR], perform the following tasks:

   (a) verifying that any information, documentation, record or other evidence required under the applicable non-aligned Union product legislation or under Regulation (EU) 2023/988 [GPSR] in relation to the product or its placing or making available on the market has been drawn up, obtained, completed, submitted, registered, affixed or otherwise provided, as applicable; where that legislation requires any such information, documentation or record to be retained, keeping it at the disposal of, or ensuring that it can be made available upon request to, the market surveillance authorities competent for the enforcement of that legislation for the period required by it;

   (b) further to a reasoned request from a market surveillance authority, providing that authority with all information and documentation necessary to demonstrate the conformity of the product in a language which can be easily understood by that authority;

   (c) when having reason to believe that a product in question is not in conformity with the relevant non-aligned Union product legislation or Regulation (EU) 2023/988 [GPSR] or presents a risk, informing the market surveillance authorities thereof;

   (d) cooperating with the market surveillance authorities, including following a reasoned request making sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in the non-aligned Union product legislation applicable to the product in question or under Regulation (EU) 2023/988 [GPSR], or, if that is not possible, to mitigate the risks presented by that product, when required to do so by the market surveillance authorities or on its own initiative, where the economic operator considers or has reason to believe that the product in question presents a risk.

2. This Article shall not apply in relation to a product that is subject to Regulation (EC) No 1223/2009, Regulation (EU) No 305/2011, Regulation (EU) 2017/745, Regulation 2017/746 or Regulation 2017/1369.

Article 11

Obligations of the economic operators with respect to the product responsibility record

1. Where the responsible economic operator established in the Union for a product is an authorised representative referred to in Article 9(2)(b)(ii), and the product is not required to have a digital product passport, the manufacturer shall create a product responsibility record in accordance with Article 83.

2. Before mandating the authorised representative referred to in paragraph 1, the manufacturer and the prospective authorised representative shall register in the registry referred to in Article 81 and store the unique operator identifiers. The registration shall be completed in accordance with Article 81(3).

3. The registry referred to in Article 81 shall store the unique operator identifier of the authorised representative, together with the data necessary to identify that economic operator and to enable searches for the products for which it is responsible.

4. The registry shall enable the digital mandate referred to in Article 9(2)(b)(ii) to be registered and its acceptance to be confirmed by the authorised representative. The registry shall link the mandate to the unique operator identifiers of the manufacturer and the authorised representative and to the product identifiers of the product or products covered by that mandate, and shall record its scope, date of effect, amendment, suspension and termination.

Chapter 2
OBLIGATIONS OF ECONOMIC OPERATORS UNDER ALIGNED UNION PRODUCT LEGISLATION

SECTION I

OBLIGATIONS OF THE MANUFACTURER AND OTHER RESPONSIBLE ECONOMIC OPERATORS ESTABLISHED IN THE UNION

Article 12

Obligations of manufacturers

1. Before a product subject to aligned Union product legislation is placed on the market or put into service, its manufacturer shall ensure that it has been designed and manufactured in accordance with the applicable essential or other substantive requirements laid down in the applicable aligned Union product legislation.

2. Before the product is placed on the market, the manufacturer shall draw up the required technical documentation and carry out the applicable conformity assessment procedure or have it carried out by a notified body.

3. Where compliance of a product with the applicable requirements laid down in the aligned Union product legislation has been demonstrated by the procedure referred to in paragraph 2, the manufacturer shall, before the product is placed on the market:

   (a) create, or have a digital product passport created for that product in accordance with Article 17(2);

   (b) affix the CE marking in accordance with the applicable provisions of Articles 18 and 19;

   (c) affix the visual identity of the digital product passport and the data carrier in accordance with Article 67(3) ;

   (d) complete the digital compliance information required under this Regulation and the applicable aligned Union product legislation and, where the CE marking or another mandatory conformity marking if required under aligned Union product legislation, digitally affix that marking in the digital product passport in accordance with the applicable provisions of Articles 18 and 19;

   (e) register the digital product passport in the registry referred to in Article 81 in accordance with Article 66 and the relevant aligned Union product legislation;

   (f) ensure a passive digital back-up of the digital product passport in accordance with Article 17(10).

4. Each manufacturer shall ensure that the technical documentation referred to in paragraph 2 is up to date and shall keep that technical documentation and the digital product passport referred to in this paragraph for a period of 10 years from the date the relevant product has been placed on the market.

5. Each manufacturer shall ensure that procedures are in place to ensure that its products that are part of a series production to remain in conformity with this Regulation and the applicable aligned Union product legislation. Changes in product design or characteristics of products, and changes in the harmonised standards, harmonised standardisation deliverables or the common specifications referred to in Article 6 by reference to which the conformity of a product is declared or by application of which its conformity is verified, shall be adequately taken into account.

   When deemed appropriate to protect the health and safety of consumers and other end-users, and where appropriate with regard to the risks presented by a product, each manufacturer shall, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.

6. The manufacturer shall ensure that each of its products bears a type, batch, serial or model number or other element allowing its identification, and that the required information is provided in the digital product passport.

7. The manufacturer shall indicate its name, registered trade name or registered trademark as well as its postal and digital contact on the product or, where that is not possible, on its packaging, in a document accompanying the product or in the digital product passport. The postal address and digital contact shall indicate a single point at or through which the manufacturer can be contacted. Where the manufacturer has designated an authorised representative for a product, it shall also indicate in the digital product passport the details of the authorised representative for that product.

8. The manufacturer shall ensure that the product is accompanied by instructions for use and safety or other public interest-related information, and, where appropriate, instructions for refurbishment, in a language or languages easily understood by consumers and other end users, as determined by the Member State concerned. The instructions for use and safety or other public interest-related information shall be clear, understandable, legible and visible, including for persons with disabilities, if feasible.

9. The instructions for use and safety or other public interest-related may be provided in electronic form. Where either is provided in electronic form, the instructions for use or safety or other public interest-related information concerned shall be included in the digital product passport.

10. Where the applicable aligned Union product legislation requires instructions for refurbishment to be provided, those instructions shall be provided in electronic form through the digital product passport.

11. The manufacturer shall take into account the intended use and the foreseeable user of the product when decided the specific format for the instructions for use and safety or other public interest-related information. In case of a product intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide the instructions for use and essential safety or other public interest-related information in paper format or shall mark those instructions for use and that essential safety or other public interest-related information on the product.

12. When drafting the instructions for use and safety or other public interest-related information, the manufacturers shall take account into the intended use and foreseeable misuse by the end user, as well as the role which instructions for use play in ensuring safety.

13. When the instructions for use and safety or other public interest-related information, referred to in paragraph 8, are provided in electronic form, the manufacturer shall:

    (a) mark on the product, or, where that is not possible, on its packaging or in an accompanying document, how to directly access those instructions for use and safety or other public interest-related information directly and how to request them in paper format;

    (b) present those instructions for use and that safety or other public interest-related information in a format that makes it possible for the end-user to print download them and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the product; that requirement also applies where the instructions for use and information are embedded in the software of the product;

    (c) make those instructions for use and that safety or other public interest-related information accessible online during the lifetime of the product and for at least 10 years after the placing on the market of the product.

14. However, the end user may, at the time of the purchase of the product, or up to 24 months after that purchase, request the instructions for use and safety or other public interest-related information in paper format. Where the end-user requests those instructions for use or that safety or other public interest-related information in paper format, the manufacturer shall provide those instructions for use or that safety or other public interest-related information to the end user, free of charge, within one month of

receiving the request. The safety or other public interest-related information shall clearly inform the end users of their right to request the instructions for use or safety or other public interest-related information in paper format.

15. Where a manufacturer considers, or has reason to believe, that a product that it has placed on the market is not in conformity with this Regulation and the applicable aligned Union product legislation, it shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or to recall it, as appropriate.

    Furthermore, where a manufacturer considers, or has reason to believe, that a product's non-conformity presents a risk, it shall immediately inform:

    (a) the market surveillance authorities of the Member States in which it has made the product available, through the Safety Business Gateway, giving details, in particular, of any non-compliance and of any corrective measures taken; and

    (b) the consumers or other end users, in accordance with Article 35 or 36 of Regulation (EU) 2023/988 or both.

16. A manufacturer shall ensure that all other economic operators, in the supply chain related to a product manufactured by it, are kept informed in a timely manner of any non-compliance that the manufacturers have identified.

17. A manufacturer shall make publicly available adequate and effective communication channels, such as a telephone number, digital contact or a dedicated section of their website, to enable consumers or other end users to submit complaints concerning the safety of the products it has manufactured and to provide information of any accident or safety issue they have experienced with such products. In doing so, the manufacturers shall take into account the accessibility needs of persons with disabilities.

18. Manufacturers shall investigate effectively, efficiently and without delay process complaints and information referred to in paragraph 5, as the case may be through investigations. They shall send a reasoned, accurate, adequate and complete reply to the physical or legal persons which have filed such complaints or provided such information. They and shall keep an internal register of those complaints and that information, as well as of recalls and any other corrective measures taken to bring the products into conformity with this Regulation and the applicable aligned Union product legislation.

19. Except for consumers or other end users who substantially modify a product for their own use, a natural or legal person shall be considered to be a manufacturer for the purposes of this Regulation and the applicable aligned Union product legislation, and shall be subject to the obligations laid down in this Article, where that person:

    (a) places a product on the market under its own name or trademark; or

    (b) substantially modifies a product already placed on the market in such a way that compliance with the applicable requirements of this Regulation or the applicable aligned Union product legislation may be affected, and subsequently makes that product available on the market.

20. Where a natural or legal person referred to in paragraph 19 is not established in the Union, it shall ensure that there is a responsible economic operator established in the Union in respect of the product, in accordance with Article 9, where the product is subject to aligned Union product legislation.

Article 13

Obligations of importers and authorised representatives

1. Where an importer or authorised representative is the responsible economic operator pursuant to Article 9, the importer or authorised representative shall, before the product is placed on the market, ensure that it complies with this Regulation and the applicable aligned Union product legislation or with Regulation (EU) 2023/988 [GPSR].

2. Before the product is placed on the market or put into service the importer or authorised representatives shall ensure the manufacturer has complied with all requirements set out in Article 12 and in the applicable aligned Union product legislation or in Regulation (EU) 2023/988 [GPSR].

3. Where prior to placing a product on the market on their behalf or on behalf of the manufacturer, respectively, an importer or authorised representatives consider, or have a reason to believe, that the said product is not in conformity with this Regulation and the applicable aligned Union product legislation or with Regulation (EU) 2023/988 [GPSR], they shall inform the manufacturer and refrain from placing the product on the market on its behalf or on behalf of the manufacturer until it has been brought into conformity.

4. Where importers or authorised representatives consider, or have a reason to believe, that a product prior to its placing on the market presents a risk, they shall:

   (a) immediately inform the manufacturer thereof; and

   (b) ensure that the market surveillance authorities are immediately informed through the Safety Business Gateway.

5. Importer or authorised representative shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential or other substantive requirements.

6. When deemed appropriate with regard to the risks presented by a product, the importer or the authorised representative shall, to protect the health and safety of consumers, carry out sample testing of marketed products.

7. Where importers or authorised representatives consider, or have a reason to believe, that a product that they have placed on the market on behalf of the manufacturer is not in conformity with the applicable aligned Union product legislation or with Regulation (EU) 2023/988 [GPSR], and the manufacturer has not taken any corrective measures, they shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or to recall it, as appropriate.

8. Where the authorised representative considers, or has a reason to believe, that a product that they placed on the market on their behalf or on behalf of the manufacturer, respectively, on behalf of the manufacturer presents a risk, they shall:

   (a) immediately inform the manufacturer thereof;

   (b) ensure that consumers or other end users are immediately informed thereof in accordance with Article 35 or 36 of Regulation (EU) 2023/988 or both; and

   (c) immediately inform the market surveillance authorities through the Safety Business Gateway, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Importers or authorised representatives shall, for a period of 10 years from the date when the product has been placed on the market on their behalf or on behalf of the manufacturer, respectively, keep the unique product identifier of the product at the disposal of the market surveillance authorities and ensure that the technical documentation referred to in Article 12(2) can be made available to those authorities, upon request.

10. Authorised representative shall take up professional liability insurance up to an amount which is proportionate to their potential maximum exposure which may result from the lack of compliance with their obligations under this Regulation and the applicable aligned Union product legislation or with Regulation (EU) 2023/988 [GPSR]. Upon the request of a market surveillance authority in the context of an investigation, authorised representatives shall present an insurance certificate or other evidence of valid insurance covering products already placed on the market and subject to that investigation.

11. Importers or authorised representatives shall verify whether the manufacturer has made communication channels as referred to in Article 12(17) publicly available to consumers or other end users, in order to allow them to submit complaints concerning the safety of products and provide information on any accident or safety issue they have experienced with the product. If communication channels are not available, importers or authorised representatives shall provide for them, taking into account accessibility needs for persons with disabilities.

12. Importer or authorised representatives shall investigate complaints and information as referred to in Article 12(18) that they have received via a communication channel made available by the manufacturer and that concern the products that they have made available on the market. Importers or authorised representatives shall file such complaints, as well as recalls and any other corrective measures taken to bring the products into conformity with this Regulation and the applicable aligned Union product legislation or with Regulation (EU) 2023/988 [GPSR], in the register referred to in Article 12(17), or in their own internal register.

    Importer or authorised representatives shall keep the manufacturer, distributors and, where relevant, providers of online marketplaces informed in a timely manner of the investigation performed and of the results of the investigation.

13. The internal register referred to in paragraph 12 shall contain only personal data that are necessary for the importer or authorised representative to investigate the complaint or the information referred to in paragraph 12. Such data shall be kept only as long as is necessary for the purposes of the investigation and, in any event, no longer than 5 years from the date the data have been entered into the internal register.

SECTION II

OBLIGATIONS OF OTHER ECONOMIC OPERATORS

Article 14

Obligations of distributors

1. When making a product available on the market, distributors shall act in relation to the requirements of this Regulation and the applicable aligned Union product legislation.

2. Before making a product available on the market or put into service, the distributors shall verify if the manufacturer has complied with all requirements set out in Article 12 and in the applicable aligned Union product legislation.

3. Where distributors consider, or have reason to believe, that a product is not in conformity with this Regulation or the applicable aligned Union product legislation, they shall inform the manufacturer, the importer, or the authorised representative and refrain from making the product available on the market until it has been brought into conformity.

   Furthermore, where distributors consider, or have reason to believe, that a product presents a risk, they shall:

   (a) immediately inform the manufacturer, the importer, or the authorised representative as applicable, thereof; and

   (b) ensure that the market surveillance authorities are immediately informed through the Safety Business Gateway.

4. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential or other substantive requirements.

5. Where distributors consider, or have reason to believe, that a product which they have made available on the market is not in conformity with this Regulation or the applicable aligned Union product legislation, they shall ensure that the corrective measures necessary to bring that product into conformity, to withdraw it or to recall it, as appropriate, are immediately taken.

   Furthermore, where distributors consider, or have reason to believe, that a product that they have made available on the market presents a risk, they shall immediately inform:

   (a) through the Safety Business Gateway the market surveillance authorities of the Member States in which they made the product available, giving details, in particular, of the non-compliance and of any corrective measures taken; and

   (b) consumers or other end users, in accordance with Article 35 or 36 of Regulation (EU) 2023/988, as the case may be.

Article 15

Obligations of fulfilment service providers

1. When contributing to the making available on the market of a product, fulfilment service providers shall act with due care in relation to the requirements that apply to them laid down in this Regulation and in the applicable aligned Union product legislation.

2. Fulfilment service providers shall ensure that the conditions during warehousing, packaging, addressing or dispatching do not jeopardise the product's conformity with the essential or other substantive requirements.

3. Where fulfilment service providers consider or have reason to believe, on the basis of the information provided by authorities or economic operators, that the product is not in conformity with this Regulation or the applicable aligned Union product legislation, they shall not support the making available of the product on the market until it has been brought into conformity.

Article 16

Obligations of refurbishers

1. This Article shall apply only in respect of products or categories of products for which the applicable aligned Union product legislation provides for the application of the refurbishment conformity assessment procedure set out in Module A-R(efurbishment) in Annex III.

2. Activities may qualify as refurbishment within the meaning of this Article only when they are conducted within the Union market territory on products that have been already placed on the Union market at a given moment during their lifecycle.

3. Before making a refurbished product available on the market or putting it into service, refurbishers shall ensure that the refurbishment has been carried out in such a way that the product continues to comply, or is brought back into compliance, with the applicable essential or other substantive requirements laid down in the aligned Union product legislation at the time the product was placed on the market or put into service.

4. Where instructions for refurbishment have been made available by the manufacturer, refurbishers shall carry out the refurbishment in accordance with those instructions and within the limits specified therein.

5. Refurbishers shall use only spare parts, components, materials, software or other elements that are identified in the instructions referred to in paragraph 4 as compatible with the product or that the refurbishers can otherwise demonstrate to be compatible with maintaining or reinstating compliance with the applicable essential or other substantive requirements. Refurbishers shall be entitled to use any spare parts, components, materials, software or other elements which have the performance and compatibility characteristics spelled out in the instructions for refurbishment and shall not be bound to use only spare parts, components, materials, software or other elements produced by the original equipment manufacturer or pre-approved by it.

6. Where the refurbishment is carried out in accordance with the instructions for refurbishment referred to in paragraph 4 and does not alter the intended purpose, type or performance of the product, change the nature of a hazard or increase the level of risk, refurbishers shall not be required to repeat the conformity assessment procedure that was originally conducted by the manufacturer in respect of aspects of the product that are not affected by the refurbishment. Refurbishers shall, however, verify and document that the refurbishment has not adversely affected the product's compliance with the applicable essential or other substantive requirements or, where compliance had been affected, that such compliance has been reinstated.

7. Refurbishers shall prepare a refurbishment report in accordance with Module A-R(refurbishment) and keep it for the period specified in the aligned Union product legislation.

8. That refurbishment report shall be:

   (a) included in the digital product passport in the field that is reserved for the refurbishment report, where a product is subject to a digital product passport issued at item level;

   (b) provided in a digital form and made available via an internet address, where a product is subject to a digital product passport issued at batch or model level, or is not subject to a digital product passport requirement.

SECTION III

DEMONSTRATION OF COMPLIANCE

Article 17

Digital product passport

1. Before a product covered by the aligned Union product legislation is placed on the market or put into service, the responsible economic operator established in the Union referred to in Article 9 shall ensure that the requirements relating to the creation and registration of the digital product passport laid down in Articles 12 and 66 and the applicable registration requirements laid down in Article 81 have been fulfilled, in accordance with their respective obligations.

   (a) Where a product falls within the scope of more than one Union legal act requiring the digital product passport, Article 64(3) shall apply.

   (b) Unless the applicable aligned Union product legislation provides otherwise, the requirements of this Article shall apply to all products falling within the scope of that legislation.

2. The manufacturer shall be the economic operator responsible for the creation and registration of the digital product passport for the purposes of Article 65 and shall comply with the corresponding obligations laid down in that Article and in Article 81.

3. The economic operator referred to in paragraph 1 which places a product on the market shall ensure, prior to placing the product on the market, that its unique operator identifier is registered in accordance with Article 81(4), point (b). The economic operator referred to in paragraph 1 which places a product on the market shall obtain a unique registration identifier prior to placing the product on the market in accordance with Article 82. The registry referred to in Article 81 shall store the unique operator identifier of the responsible economic operator referred to in paragraph 1, together with the data necessary to identify that economic operator and to enable searches for the products for which it is responsible.

4. Where the responsible economic operator referred to in paragraph 1 is an authorised representative, the registry shall enable the digital mandate referred to in Article 9(2)(b)(ii) to be registered and its acceptance to be confirmed by the authorised representative. The registry shall link the mandate to the unique operator identifiers of the manufacturer and the authorised representative and to the unique product identifier of the product or products covered by that mandate, and shall record its scope, date of effect, amendment, suspension and termination.

5. The digital product passport, the data carrier and the unique identifiers used therein shall comply with the requirements laid down in Articles 66, 67, 72 and 73. Unless the applicable aligned Union product legislation provides otherwise, the digital product passport shall be accessible to:

   (a) economic operators referred to in Article 12 to Article 16 and providers of online marketplaces as defined in Article 4, first paragraph, point(18);

   (b) market surveillance authorities as defined in Article 4, first paragraph, point (56) and customs authorities;

   (c) consumers and other end users.

6. Unless the applicable aligned Union product legislation provides otherwise, no distinction shall be made between the access rights of the actors referred to in the first subparagraph regarding the information listed in Annex II.

7. For the purposes of Article 65(1), point (d), the digital product passport shall be created at model level and shall ensure the traceability of the product in accordance with Article 68(2) and (3), unless the applicable aligned Union product legislation provides otherwise.

8. For the purposes of Article 65(1), point (b), the digital product passport shall contain all the information listed in Annex II. Where the applicable aligned Union product legislation requires additional information to be included or allows additional information to be included on a voluntary basis, such additional information may be included only if it complies with Article 67(7).

9. For the purposes of Article 65(1), point (f) the digital product passport shall be stored by the manufacturer or by a digital product passport service provider and shall remain available for a period of 10 years after the date on which the product was placed on the market.

10. For the purposes of Article 65(2), point (e), the manufacturer shall ensure that a passive digital back-up of the digital product passport is set up and maintained in accordance with Article 75(2), point (b) for the same period referred to in paragraph 9.

11. A validity of the digital product passport shall be assessed in accordance with article 66(6). Failure to comply with any of the requirements laid down in this Article by supplying incorrect information shall lead to the imposition of penalties in accordance with the rules laid down in Articles 139 to 143.

Article 18

Physical affixing of the CE marking

1. Until [*insert date 5 years after the date of entry into application of this Regulation*], the requirement to affix the CE marking shall be fulfilled by the manufacturer by physically affixing the CE marking in accordance with this Article. That requirement shall apply irrespective of whether the CE marking is additionally digitally affixed in accordance with Article 19.with Article 19.

2. The CE marking as presented in Annex IV shall be affixed only to products to which its affixing is provided for by the applicable aligned Union product legislation and shall not be affixed to any other product.

3. Where the CE marking is physically affixed, it shall be affixed before the product is placed on the market or put into service and only after:

   (a) the applicable conformity assessment procedure has been completed;

   (b) compliance with the applicable essential or other substantive requirements has been demonstrated.

4. By physically affixing or having physically affixed the CE marking, the manufacturer declares that the product complies with all applicable requirements of this Regulation and the applicable aligned Union product legislation providing for its affixing and assumes responsibility for the conformity of the product.

5. This Article shall cease to apply from [insert date 5 years after the date of entry into application of this Regulation]. From that date, the requirement to affix the CE marking

shall be fulfilled in accordance with Article 19. This shall not affect the legal effect of a CE marking physically affixed in accordance with this Article to a product placed on the market or put into service before that date.

Article 19

Digital affixing of the CE marking

1. During the period in which Article 18 applies, the manufacturer may digitally affix the CE marking, in addition to and on a voluntary basis alongside the physical affixing required according to that Article. From the date on which Article 18 ceases to apply, the manufacturer shall digitally affix the CE marking for products for which the applicable aligned Union product legislation requires that marking. Where the CE marking is digitally affixed, it shall be encoded into the appropriate field within the digital product passport before the product is placed on the market or put into service and only after:

   (a) the applicable conformity assessment procedure has been completed;

   (b) compliance with the applicable essential or other substantive requirements has been demonstrated; and

   (c) all digital compliance information required before the product is placed on the market or put into service has been entered in the digital product passport.

2. The CE marking shell be deemed digitally affixed upon registration of the relevant digital product passport in the registry. By such registration, the manufacturer declares that the product complies with all applicable requirements of this Regulation and the applicable aligned Union product legislation providing for its affixing and assumes responsibility for the conformity of the product and for the accuracy and completeness of the digital compliance information referred to in paragraph 2, point (c).

3. The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the applicable aligned Union product legislation providing for its affixing.

4. The affixing of any markings, sign or inscription or other element that is likely to mislead third parties as to the meaning, form or legal effect of the CE marking, or as to the product to which it related, shall be prohibited. Any other marking may be affixed provided that it does not impair the visibility, legibility, meaning or legal effect of the CE marking.

5. Member States shall ensure the correct application of the rules laid down in this Article and, for the period during which Article 18 applies, in that Article and shall take appropriate action in the event of its improper or fraudulent use. Penalties applicable to infringements of those rules shall be effective, proportionate and deterrent.

Chapter 3
OBLIGATIONS OF PROVIDERS OF ONLINE

MARKETPLACES AND OF ECONOMIC OPERATORS USING AN ONLINE INTERFACE

Article 20

Substantive obligations of providers of online marketplaces and economic operators offering products online

1. Before allowing that the offer of a specific product that targets end-users in the Union is listed on their platforms, providers of online marketplaces shall verify that:

   (a) with respect to a product requiring a digital product passport pursuant to Article 64:

      i. a valid digital product passport exists for that product; and

      ii. that offer corresponds to the valid digital product passport of that product; and

   (b) with respect to a product requiring a product responsibility record pursuant to Article 83:

      i. a valid product responsibility record exists for that product; and

      ii. that offer corresponds to the valid product responsibility record of that product.

2. If providers of online marketplaces receive a notification from the registry established under Article 81 to the effect that the digital product passport referred to in Article 64 or the product responsibility record referred to in Article 83 is no longer valid, they shall:

   (a) remove from their platform the offer of the product whose digital product passport or a product responsibility record has become invalid and the offers of products sharing the same identifiers as that product; and

   (b) prevent the reappearance of offers of non-compliant products sharing the same identifiers as the product whose digital product passport or a product responsibility record has become invalid.

   The notification shall constitute an order to remove taken by a market surveillance authority pursuant to Article 92(4), point (k)(i) and within the meaning of Article 9 of the Digital Services Act Regulation.

3. After fulfilling their obligations under paragraph 1, and before allowing that the offer of a specific product that targets end-users in the Union is listed on their platforms, the providers of online marketplaces shall notify the merchant by automated means the product identifier that was assigned to the product in the registry established under Article 81.

4. Providers of online marketplaces shall develop a software that enables the actions required to fulfil the obligations laid out in paragraph 1 to paragraph 2 in a way that is automated so that it does not require them to carry out an independent assessment of that content. The Commission shall adopt an implementing act to lay down the necessary operational details and the software requirements. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 136(3).

5. Providers of online marketplaces shall, in respect of a specific product, fulfil the obligations of an authorised representative referred to in Article 10, if that product requiring a digital product passport laid out in Article 64, or referred to in Article 10, if that product is requiring a product responsibility record as laid out in Article 83, where:

   (a) they do not fulfil the obligations laid down in paragraph 1 and paragraph 2; and

   (b) that product is placed on the market without an economic operator that is established in the Union responsible for it.

6. The requirements and obligations laid down in paragraph 1 to paragraph 5 shall apply *mutatis mutandis* to any manufacturer, importer, authorised representative or refurbisher that uses an online interface to target end-users in the Union.

Article 21

Procedural and due diligence obligations of providers of online marketplaces and economic operators offering products online

1. A provider of an online marketplace shall register with the EU Market Surveillance Data Hub referred to in Article 128.

2. Without prejudice to Article 11 of Regulation (EU) 2022/2065, providers of online marketplaces shall designate a single point of contact allowing them to communicate directly and effectively on the compliance of products with the Union harmonisation legislation, by electronic means, with market surveillance authorities in the exercise of their powers laid down in this Regulation. The single point of contact designated pursuant to this paragraph may be the same as the ones designated under Article 22(1) of Regulation (EU) 2023/988 and under Article 11(1) of Regulation (EU) 2022/2065. Providers of online marketplaces shall indicate in the EU Market Surveillance Data Hub referred to in Article 128 the details of the single contact point.

3. Without prejudice to Article 12 of Regulation (EU) 2022/2065, providers of online marketplaces shall designate a single point of contact to enable users to communicate directly and effectively with them in relation to compliance of products with the Union harmonisation legislation.

4. Providers of online marketplaces shall ensure that they have internal processes in place for product compliance in order to comply without undue delay with the relevant requirements of this Regulation as well as with Articles 30 and 31 of Regulation (EU) 2022/2065.

5. Providers of online marketplaces that receive an order to remove issued by a market surveillance authority pursuant to Article 92(4), point (k)(i) through the European Product Act Registry referred to in Article 81, pursuant to Article 116(4), point (c)(i), or pursuant to Article 125 by an authority referred to in Article 121(1) and (2), shall act without undue delay, and at the latest within two working days from receipt of the order. The search for the content concerned shall be limited to the information identified in the order and shall not require the provider of an online marketplace to carry out an independent assessment of that content and the removal may be carried out in a proportionate manner by reliable automated tools. Providers of online marketplaces shall, without undue delay and at the latest within four working days from the date of the removal, inform the issuing authority via the EU Market

Surveillance Data Hub referred to in Article 128 and the Safety Gate Portal referred to in Article 34(3) of Regulation (EU) 2023/988 accordingly.

6. Member States shall ensure that the orders to remove issued pursuant to Article 92(4), point (k)(i) at least include:

   (a) a reference to the legal basis under Union or national law for the order;

   (b) a statement of reasons explaining why the product is non-compliant, by reference to one or more specific provisions of Union law or national law in compliance with Union law;

   (c) information identifying the issuing market surveillance authority;

   (d) clear information enabling the provider of online marketplace to identify and locate the content concerned, such as one or more exact URL and, where necessary, additional information;

   (e) information about redress mechanisms available to the provider of online marketplace and to the economic operator who put the product concerned on the market; and

   (f) where applicable, information about which authority is to receive the information about the effect given to the orders.

7. Providers of online marketplaces shall take into account regular information on non-compliant products notified by the market surveillance authorities through the EU Market Surveillance Data Hub referred in Article 128 for the purpose of applying their voluntary measures aimed at detecting, identifying, removing or disabling access to the content referring to offers of non-compliant products on their online marketplace. Where providers of online marketplaces take one of those measures, they shall inform thereof the authority that made the notification to the EU Market Surveillance Data Hub of any action taken without delay.

8. Providers of online marketplaces shall, without undue delay and in any event within two working days from the receipt of a notice from market surveillance authorities pursuant to Article 16 of Regulation (EU) 2022/2065 or Article 127(2), process the notices related to product compliance issues with regard to the product offered for sale online through their services.

9. For the purpose of complying with the requirements of Article 31(1) and (2) of Regulation (EU) 2022/2065 as regards product compliance information, providers of online marketplaces shall design and organise their online interface in a way that enables traders offering the product to provide at least the following information for each product offered and that ensures that the following information is displayed or otherwise made easily accessible by end users on the product listing:

   (a) name, registered trade name or registered trademark of the manufacturer, as well as the postal and electronic address at which the manufacturer can be contacted;

   (b) where the manufacturer is not established in the Union, the name, postal and electronic address of the responsible economic operator within the meaning of Article 9;

   (c) a valid digital product passport, if such product is requiring a digital product passport laid out in Article 64, or a valid Product Responsibility Record laid out in Article 83;

(d) information allowing the identification of the product, including a picture of it, its type and any other product identifier; and

(e) any warning or safety or other public interest-related information to be affixed on the product or to accompany it in the digital product passport in accordance with the applicable Union product legislation listed in Annex I in a language which can be easily understood by consumers and other end users as determined by the Member State in which the product is made available on the market.

10. For the purposes of this Regulation, Article 23 of Regulation (EU) 2022/2065 shall be understood to the effect that providers of online marketplaces shall suspend, for a reasonable period of time and after having issued a prior warning, the provision of their services to traders that repeatedly offer products which are non-compliant with this Regulation.

11. Providers of online marketplaces shall cooperate fully, effectively and speedily with the market surveillance authorities, customs authorities, traders and relevant economic operators to facilitate the adoption and the effective application of any action taken to eliminate or, if that is not possible, to mitigate the risks presented by a product that is or was offered online through their services.

In particular, providers of online marketplaces shall:

(a) provide appropriate and timely information to end users including by:

i. directly notifying all affected end users who bought through their interfaces the product where a product recall occurs of which they have or should have actual knowledge and where certain information shall be brought to the attention of end users regarding product compliance to ensure the safe use of a product (the 'safety warning') in accordance with Article 35 or Article 36 of Regulation (EU) 2023/988;

ii. publishing information on recalls of the product concerned;

(b) inform the relevant economic operator of the decision to remove or disable access to the content containing or referring to an offer of a non-compliant product or any product presenting a similar risk;

(c) cooperate with market surveillance authorities and with relevant economic operators to ensure effective product recalls, including by abstaining from obstructing product recalls;

(d) immediately inform, through EU Market Surveillance Data Hub referred to in Article 128, the market surveillance authorities of the Member States in which the relevant product has been made available on the market about non-compliant products that were offered on their online interfaces to the extent that they have actual knowledge or should have that knowledge; in that context they shall provide in particular the appropriate details available to them of the risk to the health or the safety of consumers, of the quantity by Member State of products still circulating on the market, if such information is available, and of any corrective measure that, to their knowledge, has already been taken;

(e) cooperate with regard to any accidents notified to them, including by:

i. informing without undue delay the relevant economic operators without delay about the information they have received regarding accidents or safety issues, where they have knowledge or should have knowledge that

the product in question was offered by those economic operators through their interfaces;

ii. notifying without undue delay through the Safety Business Gateway of any accident, of which they have been informed, where it results or is likely to result in a serious risk or actual damage to the health or safety of an end user.

(f) cooperate with law enforcement agencies at Union and national level, including the European Anti-Fraud Office (OLAF) and customs authorities, through regular and structured exchanges of information on offers that they have removed in accordance with this Article;

(g) allow access to their interfaces to market surveillance authorities so that they can use their online tools on such interfaces with a view of identifying non-compliant products;

(h) cooperate in identifying the supply chain of non-compliant products inter alia by responding to data requests where the relevant information is not publicly available;

(i) upon a reasoned request of the market surveillance authorities, when providers of online marketplaces or online sellers have put in place technical obstacles to the extraction of data from their online interfaces (data scraping), allow the scraping of such data only for product compliance purposes and on the basis of the identification parameters provided by those market surveillance authorities.

TITLE III

CONFORMITY ASSESSMENT AND ACCREDITATION

Chapter 1
CONFORMITY ASSESSMENT OF THE PRODUCTS SUBJECT TO ALIGNED UNION PRODUCT LEGISLATION

Article 22

Conformity assessment procedures

1. Where the aligned Union product legislation and the relevant non-aligned Union product legislation requires conformity assessment to be performed in respect of a particular product, the procedures which are to be used shall be chosen from among the modules set out and specified in Annex III in accordance with the following criteria:

   (a) appropriateness of the module concerned to the type of product;

   (b) the extent to which conformity assessment corresponds to the type and degree of risk entailed by the product;

   (c) where third party involvement is mandatory, the need for the manufacturer to have a choice between quality assurance and product certification modules set out in Annex III;

   (d) least burdensome module in relation to the risks covered by the legislation concerned.

2. Manufacturers shall use the conformity assessment procedures listed in Annex III which have been retained by the respective aligned Union product legislation or the relevant non-aligned Union product legislation.

3. Where the applicable conformity assessment procedure requires the involvement of a notified body, the manufacturer shall submit the application for conformity assessment and the information and documentation required for that procedure electronically to the notified body through NANDO, in accordance with the implementing acts adopted pursuant to paragraph 6.

4. The notified body shall record in NANDO the outcome of the conformity assessment procedure and shall upload, as applicable, the certificate, attestation, decision or other conformity assessment document issued in relation to that procedure. The notified body shall also record any amendment, supplement, restriction, suspension, withdrawal or other change in the status of such document.

5. Where a notified body has been involved in the applicable conformity assessment procedure, the manufacturer shall ensure that the identification number of that notified body and a link, made available through NANDO, to the certificate, attestation, decision or other conformity assessment document issued by that notified body, as applicable, are uploaded in the registry referred to in Article 81.

6. The Commission shall adopt an implementing act in accordance with the examination procedure referred to in Article 136(3) laying down the detailed rules and uniform

conditions for the electronic submission, exchange, recording and management of information and documents through NANDO pursuant to paragraph 2 and this subparagraph. Those implementing acts shall in particular specify:

(a) the technical procedures for the electronic submission of applications for conformity assessment and accompanying information and documentation;

(b) the identification and authentication of manufacturers, notified bodies and persons acting on their behalf;

(c) the data formats, document formats and minimum data necessary for the submission, identification and traceability of applications and conformity assessment documents;

(d) the procedures for acknowledging receipt of applications and for the secure electronic exchange of information and documents between manufacturers and notified bodies;

(e) the procedures for the recording and uploading by notified bodies of certificates, attestations, decisions and other conformity assessment documents, and for recording their amendment, supplement, restriction, suspension, reinstatement, withdrawal or other change of status;

(f) the technical arrangements for linking information and documents stored in NANDO to the registry referred to in Article 81;

(g) the access rights and technical safeguards necessary to ensure the security, integrity and confidentiality of information and documents, including the protection of personal data and trade secrets.

Chapter 2
NOTIFICATION AND MONITORING OF NOTIFIED BODIES

Article 23

Notification of conformity assessment bodies by the notifying authorities

1. Member States shall notify the Commission and the other Member States the bodies authorised to carry out third-party conformity assessment tasks in accordance with the respective Union harmonisation legislation through NANDO.

2. 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 for the purposes of the respective Union harmonisation legislation, and for the monitoring of notified bodies, including compliance with Article 22 to Article 49.

3. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body.

4. 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 24. In addition, that body shall have arrangements to cover liabilities arising out of its activities. The notifying authority shall take full responsibility for the tasks performed by the body referred to in this paragraph.

5. When the notifying authority designated pursuant to paragraph 1 sets up and carries out itself the necessary procedures for the assessment and notification of conformity assessment bodies, the designating Member State shall ensure that the notifying authority has all the resources necessary to perform the technical and administrative tasks connected with its responsibilities in an appropriate, efficient and effective manner and that it complies with the requirements and obligations laid down in this Chapter.

Article 24

Requirements related to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies or other undertakings occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity, effective independence and impartiality of its activities. All personnel who participate in, or could otherwise influence, the assessment, notification or monitoring of conformity assessment bodies shall act objectively and shall be free from any undue commercial, financial or other pressure that could compromise their objectivity or impartiality.

3. A notifying authority shall require all personnel referred to in paragraph 2 to disclose any actual or potential conflict of interest as soon as it arises or becomes known to them. The notifying authority shall establish appropriate procedures for assessing and managing such conflicts of interest, including, where necessary, the exclusion of the person concerned from the relevant activities or decisions.

4. Any person who has held a governance or decision-making role in a conformity assessment body, or in an association representing conformity assessment bodies shall be prohibited, for a period of at least three years from the date on which that role ended, from participating in:

   (a) the governance or management of the notifying authority; or

   (b) decisions concerning the assessment, notification or monitoring of conformity assessment bodies.

5. A notifying authority shall be organised in such a way that each decision relating to the notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment of that body.

6. A notifying authority shall not offer or provide any activities performed by conformity assessment bodies, nor shall it offer or provide consultancy or other services as defined in Article 57 TFEU.

7. A notifying authority shall safeguard the confidentiality of the information it obtains, in accordance with Union and national law.

8. A notifying authority shall have a sufficient number of competent personnel and adequate resources at its disposal for the proper performance of its tasks. In particular, the personnel of the notifying authority shall have sound technical and vocational training covering all relevant conformity assessment activities and in-depth knowledge and understanding of the requirements laid down in the respective Union harmonisation legislation.

9. A notifying authority shall monitor the nature, scope, volume and manner of performance of the conformity assessment tasks performed by subsidiaries of or subcontractors to notified bodies in accordance with Article 38. That monitoring shall include verification that such tasks are carried out under the responsibility, supervision and control of the notified body and in compliance with the requirements applicable to notified bodies, including requirements relating to competence, independence, impartiality, confidentiality and the avoidance of conflicts of interest.

10. Member States shall inform the Commission of their rules related to the procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

11. The Commission shall make the information referred to in paragraph 10 publicly available.

Article 25

Notification procedure

1. A conformity assessment body shall submit an application for notification in accordance with this Regulation and the applicable Union harmonisation legislation to the notifying authority of the Member State in which it is established.

2. The application referred to in paragraph 1 shall be accompanied by a description of the conformity assessment activities and the products for which that body claims to be competent, and where relevant by an accreditation certificate issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 22 to Article 49.

3. Notifying authorities may only notify conformity assessment bodies which have satisfied the requirements laid down in Article 22 to Article 49.

4. Notifying authorities shall notify conformity assessment bodies to the Commission and the other Member States through NANDO.

5. The notification referred to in paragraph 4 shall include full details of the conformity assessment activities and the relevant accreditation certificate. The notification shall also include information on any tasks to be performed by subsidiaries and subcontractors.

6. Where a notification is not based on an accreditation certificate referred to in para, 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 22 to Article 49.

7. 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 months following the date on which the Commission validates the notification.

8. Only the body referred to in paragraph 7 shall be considered to be a notified body for the purposes of the respective Union harmonisation legislation.

9. The notifying authority shall inform the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 4.

Article 26

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to each notified body.
2. It shall assign a single identification number even where the same body is notified pursuant to several Union harmonisation legislations.
3. The Commission shall make publicly available an up-to-date list of bodies notified pursuant to the Union harmonisation legislations, including the identification numbers that have been assigned to them and the activities for which they have been notified.

Article 27

Monitoring and reassessment of notified bodies

1. If no objections against a notification are raised pursuant to Article 25(7), the notified body concerned may perform the activities for a maximum of 5 years from the date of submission of the notification. The notified bodies shall not conduct assessments and deliver certificates until the respective objection period provided for in Article 25(7) has expired.
2. No later than 3 months prior to the date of expiration of the activity period referred to in paragraph 1, the notified body shall resubmit an application for renewal of the notification. The required supporting elements and the procedure for the processing of this notification shall be the same as laid down in Article 25.
3. Where a notified body applies for the renewal of its notification pursuant to paragraph 2, and the notifying authority has been informed in accordance with paragraph 4, that a significant number of products in respect of which conformity assessment activities were carried out by that notified body have been found to be non-compliant, the notifying authority shall reject the renewal application
4. Notifying authorities shall reject the request where one or more of the following conditions are met:
   (a) during the preceding two years, at least three market surveillance authorities have informed the notifying authority of non-compliant products in respect of which conformity assessment activities were carried out by the notified body concerned;
   (b) the Commission has informed the notifying authority that non-compliant products in respect of which conformity assessment activities were carried out by the notified body concerned pose a significant risk of disruption to the functioning of the internal market;
   (c) during the preceding two years, at least three economic operators have informed the notifying authority of substantiated concerns regarding the impartiality of the notified body or its handling of commercially sensitive information;
   (d) during the preceding two years, the notified body has not carried out any conformity assessment activities within all or part of the scope of its notification.
5. Notifying authorities shall suspend the procedure for renewal of the notified body in the case where there is an ongoing administrative or judicial procedure at national or Union level as regards the competence of a notified body, until that investigation has been concluded.

Article 28

Periodical review of notified bodies' assessments by the notifying authorities

1. As part of their monitoring activities, notifying authorities shall perform reviews of the assessments conducted by the conformity assessment bodies that they have notified.

2. The reviews referred to in paragraph 1 shall be performed once per year for each notified body and shall be based on a randomly selected sample of at least 5 % of the technical files that the notified body processed during the year preceding the review.

3. As part of coordinated campaigns coordinated by the Commission, the notifying authorities may perform *ad hoc* reviews targeting specific types of products or sectors. Such *ad hoc* reviews shall be conducted in addition to the regular yearly reviews to be conducted pursuant to paragraph 2.

4. Depending on the outcome of the reviews, notifying authorities may trigger the procedure laid down in Article 30.

Article 29

Reassessment of a notified body by the Commission

1. Where the conditions laid down in Article 27(4) are met and a notifying authority fails to limit the validity of the notification to a period not exceeding two years, the Commission may request the notifying authority to justify its inaction within two weeks of the receipt of that request.

2. Where the notifying authority fails to provide a justification within the period referred to in paragraph 1 or where the justification provided is not sufficiently substantiated, the Commission may adopt a decision suspending all or part of the notification of the notified body concerned and relieving the notifying authority from the responsibility to conduct the reassessment of the notified body. The suspension shall apply pending the adoption of the implementing decision referred to in paragraph 5.

3. The notifying authority shall provide the Commission without delay all information and documentation relevant to the reassessment referred to in paragraph 1, including the information and documentation on which the notification was based and the results of any previous monitoring or reassessment of the notified body.

4. The notified body concerned, shall at the request of the Commission provide all information and supporting evidence necessary to demonstrate that it complies with the applicable requirements and fulfils the responsibilities entrusted to it pursuant to Article 22 to Article 49.

5. The Commission shall without undue delay examine all the information and evidence provided by the notified body pursuant to paragraph 4. Where the Commission deems necessary to ascertain the information provided by the notified body pursuant to paragraph 4, the Commission may request the notifying authority concerned to verify its accuracy and report back to the Commission within a time limit specified in the request. After having examined the information and evidence provided, the Commission shall adopt an implementing decision according to the advisory procedure referred to in Article 136(2) determining whether the conformity assessment body having applied for a reassessment complies with all the applicable requirements and fulfils the responsibilities entrusted to it pursuant to Article 22 to Article 49. That

implementing decision shall state the reasons on which it is based and shall specify the scope of the notification to which it applies.

6. Where the Commission decides in accordance with paragraph 5 that the notified body complies with the applicable requirements and fulfils the obligations, the Commission shall lift any suspension imposed pursuant to paragraph 2. The notification shall remain valid for the period specified in the implementing decision, which shall not exceed two years from the date of adoption of that decision. During that period, the notifying authority shall remain responsible for the monitoring the compliance of the notified body with the applicable requirements referred to in paragraph 5. Before the expiry of that period, to the notifying authority shall reassess the notified body in accordance with Article 27.

7. Where the Commission determines pursuant to paragraph 5 that the notified body does not comply with the applicable requirements or does not fulfil the obligations incumbent upon it, it shall, taking account of the seriousness of the non-compliance, adopt an implementing decision restricting, suspending or withdrawing all or part of the notification. The notifying authority shall, without delay, take all measures necessary to give effect to that decision and to address the consequences for certificates or other conformity-assessment decisions issued by the notified body.

8. The Commission shall inform the notifying authority, the notified body concerned and the other Member States of decisions taken pursuant to this Article through NANDO.

Article 30

Challenge to the competence of notified bodies at national level

1. Where a notifying authority has reasonable grounds to doubt whether a notified body continues to possess the required competence or to comply with the requirements and fulfil the obligations to which it is subject, it shall investigate the matter without undue delay.

2. Notified bodies subject to an investigation pursuant to paragraph 1 shall fully cooperate with the notifying authority and shall provide within a period of two weeks of receipt of a request all information and supporting evidence necessary to demonstrate that they comply with the applicable requirements. Where a notified body fails to provide the requested information or evidence within that period, the notifying authority may continue the investigation and adopt a decision on the basis of the information available to it.

3. The notifying authority shall, without undue delay examine all the information and evidence available to it and shall give the notified body an opportunity to submit its observations. It shall, within a period of one month of receiving the information and evidence requested pursuant to paragraph 1, or of the expiry of the period referred to in that paragraph, adopt a reasoned decision determining whether the notified body complies with all the applicable requirements and fulfils its obligations.

   In duly justified cases, having regard to the complexity of the investigation, the notifying authority may extend that period once by no more than one month. It shall inform the notified body of the extension and the reasons for it before the expiry of the initial period.

4. Where necessary in view of the seriousness of the alleged non-compliance and the potential risks to the public interests protected by the applicable Union product

legislation or to the proper functioning of the internal market, the notifying authority may, as an interim measure, restrict or suspend all or part of the notification pending the completion of the investigation. The notifying authority shall review the measure regularly and shall lift or modify it as soon as the grounds on which it was based no longer apply. In urgent cases, the measure may be adopted before the notified body has submitted its observations, provided that it is given an opportunity to do so without undue delay after the adoption of the measure.

5. Where the notifying authority establishes a case of non-compliance, it shall, having regard to the seriousness, extent and duration of the non-compliance, take one or more of the following measures:

(a) corrective actions to be implemented by the notified body within a prescribed period and, where necessary, restrict or suspend all or part of the notification until those corrective actions have been completed;

(b) restricting all or part of the notification for a specified period of up to one year or until the notifying authority has verified that compliance has been restored;

(c) withdrawal all or part of the notification.

The notifying authority shall monitor the implementation of any corrective actions required pursuant to point (a). A restriction or suspension shall be lifted only after the notifying authority has verified that the notified body has restored compliance. A restriction, suspension or withdrawal of a notification shall not automatically affect the validity of certificates or other conformity-assessment decisions issued before the measure took effect. The notifying authority shall assess without undue delay whether, and to what extent, those certificates or decisions remain reliable and valid, taking into account:

(a) the nature and seriousness of the non-compliance established in relation to the notified body;

(b) whether the non-compliance affected the conformity-assessment activities on which the certificates or decisions were based;

(c) the risks presented by the products concerned and any non-compliance with applicable substantive requirements; and

(d) the possibility of having the relevant files and certificates reviewed or assumed by another notified body.

6. The decision referred to in paragraph 5 shall specify the measures to be taken in respect of the certificates or conformity-assessment decisions concerned, including, where appropriate, their review, restriction, suspension, withdrawal or transfer to another notified body.

7. Where the notification of a notified body has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the economic operators concerned no later than 10 working days after receiving the decision. It shall inform them of the scope and consequences of the measure and of any action that they are required to take in relation to the products or certificates concerned.

8. In the event of restriction, suspension or withdrawal of a notification, or where a notified body has ceased its activities, the notifying authority shall take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available to authorities in other Member States

responsible for notified bodies and to authorities responsible for market surveillance at their request.

9. Notifying authorities shall inform the other Member States and the Commission via NANDO, without undue delay of :

(a) the opening of an investigation pursuant to paragraph 1 where the matter may have cross-border implications;

(b) any interim measure adopted pursuant to paragraph 4; and

(c) any decision adopted pursuant to paragraph 3, paragraph 5 or paragraph 8.

Article 31

Challenge to the competence of notified bodies at Union level

1. Where the Commission has reasonable grounds to doubt, or receives information giving rise to reasonable ground to doubt as to the competence of a notified body or the continued fulfilment by a notified body of the requirements and obligations to which it is subject, and the notifying authority fails to open an investigation in accordance with Article 30, the Commission may request that notifying authority to provide, within two weeks of receipt of the request, a reasoned justification for not opening such an investigation.

This paragraph shall also apply where the information giving rise to the doubts concerns the continued validity or scope of an accreditation certificate and the national accreditation body concerned has not investigated that information.

2. Where the notifying authority does not provide a justification within the period referred to in paragraph 1, or where the justification provided does not sufficiently demonstrate why an investigation is not launched, the Commission may open an investigation into the alleged non-compliance of the notified body concerned.

3. The Commission shall inform, the notifying authority, the notified body concerned, as well as all the other Member States without undue delay of the opening of an investigation pursuant to paragraph 2.

4. Following the opening of the investigation, the notifying authority concerned shall, within a period of two weeks of receipt of a request by the Commission, provide the latter with all the information and documentation relevant to the investigation, including:

(a) the information and documentation on which the notification was based;

(b) any accreditation certificate and the corresponding assessment and monitoring reports;

(c) the results of any monitoring, reassessment or previous investigation of the notified body; and

(d) any complaints, reports or other information relevant to the continued competence or compliance of the notified body.

5. Notified bodies subject to an investigation pursuant to paragraph 2 shall fully cooperate with and the Commission and shall provide it, within two weeks of receipt of a request, with all the information and supporting evidence necessary to demonstrate that they comply with the applicable requirements and fulfil their obligations.

Where the notified body fails to provide the requested information or evidence within that period, the Commission may continue the investigation and adopt a decision on the basis of the information available to it.

6. The Commission shall give the notified body concerned and the notifying authority an opportunity to submit their observations within two weeks from the receipt of the decision. In urgent and justified cases, an interim measure referred to in Article 32(3) may be adopted before those observations have been submitted, provided that an opportunity to submit observations is given without undue delay after the adoption of that measure.

7. The Commission shall, without undue delay, examine all the information and evidence available to it. It shall adopt a reasoned implementing decision in accordance with the examination procedure referred to in Article 136(3), determining whether the notified body complies with all the applicable requirements and fulfils its obligations.

The implementing decision shall specify the scope of the notification and the conformity-assessment activities to which the Commission's findings relate.

Article 32

Measures against non-compliant notified bodies at Union level

1. Where the Commission establishes according to Article 31 that the notified body does not comply with the applicable requirements or does not fulfil the obligations incumbent upon it, the Commission shall, having regard to the seriousness, extent and duration of the non-compliance, prescribe one or more of the following measures in the implementing decision referred to in Article 31(7):

   (a) corrective actions to be implemented by the notified body within a prescribed period and, where necessary, restrict or suspend all or part of the notification until those corrective actions have been satisfactorily completed;

   (b) restriction all or part of the notification for a specified period of up to one year or until the compliance has been restored;

   (c) withdrawal all or part of the notification.

The notifying authority shall, without undue delay, take all measures necessary to give effect to the implementing decision and shall inform the Commission of the measures taken.

2. Where the Commission requires corrective actions pursuant to paragraph 1, point (a), the notification shall remain restricted or suspended, to the extent specified in the implementing decision, until the Commission or the notifying authority, as specified in that decision, has verified that compliance has been restored. A restriction, suspension or withdrawal of a notification shall not automatically affect the validity of certificates or other conformity-assessment decisions issued before the measure took effect. The Commission shall determine whether, and to what extent, those certificates or decisions remain valid, by taking into account all relevant factual and legal elements, in particular::

   (a) the nature and seriousness of the non-compliance established in relation to the notified body;

   (b) whether that non-compliance affected the conformity-assessment activities on which the certificates or decisions were based;

(c) the risks presented by the products concerned and any non-compliance with applicable substantive requirements; and

(d) the possibility of having the relevant files and certificates reviewed or assumed by another notified body.

The implementing decision referred to in Article 31(7) shall specify the measures to be taken in respect of the certificates or conformity-assessment decisions concerned, including, where appropriate, their review, restriction, suspension, withdrawal or transfer to another notified body.

3. Where necessary in view of the seriousness of the alleged non-compliance and the potential risks to the public interests protected by the applicable Union product legislation or to the proper functioning of the internal market, the Commission may, as an interim measure, restrict or suspend all or part of the notification pending the completion of the investigation referred to in Article 31(2).

4. The interim measure shall be proportionate, shall state the reasons on which it is based and shall specify its scope and duration. The Commission shall review the measure regularly and shall lift or modify it as soon as the grounds on which it was based no longer apply.

5. Where imperative grounds of urgency so require, the Commission shall adopt an immediately applicable implementing act in accordance with the procedure referred to in Article 136(4).

6. The Commission shall ensure that confidential information obtained in the course of an investigation under this Article is protected in accordance with applicable Union law.

7. The Commission shall inform the Member States and the notified body concerned of any decisions taken pursuant to this Article through NANDO.

Chapter 3
REQUIREMENTS OF NOTIFIED BODIES

Article 33

Legal status of notified bodies

1. For the purposes of notification, a notified body shall meet the requirements laid down in this chapter.

2. A notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement for the mutual recognition of results of conformity assessment procedures, and have legal personality. Its legal personality and status shall be fully documented. Such documentation shall include information about ownership and the legal or natural persons exercising control over the notified body.

3. Where a notified body is established under the law of a third country pursuant to an agreement concluded between the Union and that third country for the mutual recognition of results of conformity assessment procedures, it shall meet the requirements applicable to notified bodies laid down in this Regulation. Compliance with such requirements shall be subject to the same assessment, monitoring and enforcement conditions as apply to notified bodies established within the Union.

4. If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements laid down in Article 34 to Article 38shall apply to both the notified body and the organisation to which it belongs.

5. If a notified body wholly or partly owns, directly or indirectly, legal entities established in a Member State or in a third country or is owned, directly or indirectly, by another legal entity, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented. Personnel of those entities performing conformity assessment activities shall be subject to the applicable requirements laid down in this Regulation.

Article 34

Independence of notified bodies

1. A notified body shall be a third-party body that is in all regards, including organisationally and operationally, independent of any economic operator or organisation having any interest, direct or indirect, actual or potential, in the outcome of the conformity assessment activities or the product it assesses. The independence of a notified body shall be assessed also by taking into account, as the case may be, its direct or indirect parent companies, subsidiaries and sister companies as well as the physical persons directly or indirectly controlling them in the sense of Article 3 of the Regulation (EC) No 139/2004 .

2. The requirement of independence shall not be construed to automatically preclude the notified body from carrying out conformity assessment activities for competing manufacturers.

3. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacture, provision, assembly, use or maintenance of products shall not assess the conformity of those products.

4. The notified body shall operate with integrity, technical competence, and effective independence, and shall maintain a governance structure that ensures impartial, objective and consistent performance of conformity assessment activities.

5. To prove independence and impartiality, the notified body shall clearly document its organisational structure, including responsibilities, reporting lines, and the functions, responsibilities and the authority of its management and of other personnel who may influence the performance of the notified body or the results of its conformity assessment activities. Where the notified body forms part of a group of undertakings, it shall also document the ownership and control structure of that group and the activities of its parent undertakings, subsidiaries, sister undertakings and other affiliated undertakings, insofar as those relationships or activities may influence, or give rise to a conflict of interest in relation to, the independence, impartiality or performance of the notified body or the results of its conformity assessment activities.

6. In any event, a notified body, its management, and all personnel responsible for carrying out conformity assessment tasks shall not:

   (a) be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties;

(b) be involved in any capacity in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities;

(c) engage in any activity that may conflict with their independence of judgement or integrity in relation to the conformity assessment activities for which they are notified;

(d) offer or provide consultancy to the manufacturer to its authorised representative or to a commercial competitor as regards the design, construction, marketing or maintenance of products or processes under assessment;

(e) have commercial or shareholding relations with any organisation which itself provides consultancy services as referred to in point (d);

(f) offer or provide management system consultancy or internal auditing to the manufacturer, its authorised representative, where the conformity assessment requires the evaluation of the client's management system.

7. The provisions laid down in this Article shall not preclude the use, installation and maintenance of assessed products to the extent that it is strictly necessary for its carrying out of conformity assessment tasks.

Article 35

Prohibition of consultancy and advisory services

1. The notified body, its management, personnel, subcontractors or related entities shall not:

(a) provide consultancy or advisory, or other services relating to the design, manufacture, testing, maintenance, marketing or placing on the market of products falling within its scope of the notification subject to assessment;

(b) be involved in market surveillance activities related to products falling within the scope of the notification referred to in Article 25.

2. The services of the notified body shall not be offered or presented as linked with the activities of an organisation that provides consultancy or advisory or other commercial services. The notified body shall not state or imply that the conformity assessment would be simpler, easier faster or less expensive if a specified consultancy organisation were used.

3. The notified body shall not prioritise the assessment of applications based on the use by the manufacturer of consultancy or other services provided by any specific entity.

Article 36

Impartiality safeguards

1. The impartiality of the notified body, its management and assessment and administrative personnel shall be effectively preserved at all times.

2. The notified body shall ensure that the activities of its subsidiaries and subcontractors do not adversely affect the confidentiality, objectivity or impartiality of its conformity assessment activities.

3. The notified body shall be responsible for identifying, preventing, monitoring and managing actual, potential and perceived conflicts of interest arising from its activities and relationships, including those of its personnel, parent companies, sister companies, subsidiaries, subcontractors and external experts.

4. The notified body shall set in place documented impartiality policies and procedures approved by management that include, inter alia, the following:

   (a) organisational arrangements ensuring that personnel responsible for conformity assessment decisions are organisationally independent in an effective way from personnel performing the evaluation activities on which those decisions are based;

   (b) procedures requiring all personnel and external experts and subcontractors, prior to their involvement in conformity assessment activities, to disclose in writing any past or present consultancy, employment or other relationships that may give rise to a real or potential conflict of interest;

   (c) procedures requiring that any conflict of interest identified is recorded, investigated and resolved in accordance with documented procedures;

   (d) requirements that all personnel and external experts and subcontractors formally declare the absence of conflicts of interest prior to undertaking any conformity assessment task;

   (e) policies and procedures ensuring that the tasks carried out by the notified body are clearly distinguished from any other activities it may perform, in order to prevent conflicts of interest and to safeguard independence and impartiality;

   (f) safeguards ensuring that financial, commercial or organisational undue pressures do not influence technical judgements, including provisions that the remuneration of personnel and external experts does not depend on the number or outcome of assessments, nor on commercial considerations that could jeopardise impartiality;

   (g) a continuous, systematic and documented process for identifying, analysing, evaluating and controlling risks to impartiality arising from the notified body's activities and relationships, including risks arising from customer relationships and situations of economic dependence on individual customers or groups of related customers, risks arising from consultancy or advisory activities or from relationships with organisations providing such services;

   (h) ongoing monitoring of the notified body's own activities and relationships, including customer relationships, as well as those of its subsidiaries and subcontractors, to ensure that no consultancy or advisory activities, or other circumstances capable of compromising independence or impartiality arise.

5. The notified body may provide regulatory information and generic guidance of a general nature, provided that such information or guidance does not compromise its independence or impartiality. Such regulatory information and generic guidance shall not include advice, recommendations or solutions related to the design, manufacture, testing or maintenance of specific products.

Article 37

Resources, facilities and equipment

1. A notified body shall be capable of carrying out all the conformity assessment tasks assigned to it by this Regulation or the relevant aligned Union product legislation and in relation to which it has been notified, irrespective of the technical solutions used by the manufacturer to comply with the essential or other substantive requirements.

2. The notified body shall have permanent and direct access to suitable and necessary facilities, equipment, laboratories located on the territory of the Union and the technical information sources and measurement capabilities required to perform conformity assessment tasks. Access to such resources provided solely through subsidiaries or subcontracting arrangements shall not, in itself, be considered permanent direct access.

3. Where subcontracted laboratories, facilities or equipment are used, the notified body shall ensure that such use is justified, documented and technically controlled, remains under its legal and operational responsibility, and does not compromise impartiality, independence of the notified body or the reliability of the results of its conformity assessment activities.

4. Equipment used for conformity assessment activities, including measurement, testing or inspection equipment, shall be maintained and, where relevant, subject to metrological control in order to ensure the technical validity of results.

Article 38

General principles and limitations of subcontracting

1. The notified body may subcontract only to other conformity assessment bodies established under the national law of a Member State, or have a recourse to its subsidiaries established under the national law of a Member State, and only for clearly defined and limited parts of its notified body activities, provided that such subcontracting or recourse does not compromise compliance with the applicable requirements and does not undermine the notified body's effective performance of its notified body activities.

2. The notified body shall not subcontract:

   (a) the auditing of quality management systems as a whole;

   (b) product-related reviews as a whole;

   (c) the evaluation of assessment results;

   (d) the adoption of conformity assessment decisions;

   (e) suspension, restriction or withdrawal of certificates;

   (f) the allocation of work to external experts or the review of their qualifications and performance;

   (g) the first and last planned inspection at the manufacturer's premises under a specific contract, as a whole.

3. The notified body shall not subcontract all, or the predominant part, of its conformity assessment activities, nor restrict its role to purely administrative or coordinating functions.

4. The notified body shall retain sufficient internal competence and capacity to direct, oversee and take responsibility for all notified body activities within its scope of

notification. The notified body shall have permanent and direct access to all the personnel necessary to carry out the activities listed in paragraph 2.

5. The notified body shall be capable of reviewing all the elements of the tasks performed by subcontractors or subsidiaries.

6. The notified body shall ensure that all subcontracted activities are carried out on its behalf and under its full responsibility.

7. The notified body shall retain responsibility for the results of subcontracted activities and for any decisions based on those activities.

8. The notified body shall establish documented procedures governing subcontracting and shall ensure that:

   (a) subcontractors and external experts meet the relevant requirements applicable to the notified body for the tasks concerned;

   (b) subcontractors and external experts do not further subcontract any work;

   (c) subcontracting arrangements are subject to written agreements covering, among other things, confidentiality, independence, impartiality and conflicts of interest;

   (d) the applicant is informed of the intention to use subcontractors or external experts prior to the launch of the assessment activities;

   (e) the applicant may withdraw its application for conformity assessment if it does not agree with the use of subcontractors or external experts by the notified body without incurring any contractual penalties.

Chapter 4
GENERAL PRINCIPLES FOR CARRYING OUT CONFORMITY ASSESSMENT BY NOTIFIED BODIES

Article 39

Organisational arrangements of notified bodies

1. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have at its disposal the necessary organisational arrangements to perform conformity assessment activities in accordance with the applicable requirements laid down in Article 37 and by the relevant Union harmonisation legislation.

2. The notified body shall have in place documented procedures in accordance with which conformity assessment activities are carried out. Such procedures shall ensure transparency, consistency and the reproducibility of conformity assessment activities.

3. The notified body shall apply the conformity assessment procedures laid down in the relevant Union harmonisation legislation in a manner that takes due account of the size of the undertaking, the sector in which it operates, its organisational structure, the degree of complexity of the product technology concerned, the impact on public interest in terms of health, safety and security and the mass or serial nature of the production process.

4. The notified body shall ensure that the availability and competence of personnel, as well as access to the necessary means, facilities and equipment, are maintained in accordance with Article 41 to Article 43.

Article 40

Use of remote techniques in conformity assessment

1. Unless the applicable aligned Union product legislation provides otherwise, a notified body may use remote techniques to perform one or more conformity assessment activities where, on the basis of a documented assessment, it concludes that those activities can be performed remotely without reducing the effectiveness, reliability or level of assurance of the conformity assessment procedure.

2. Remote techniques shall complement and shall not replace on-site conformity assessment where physical presence is necessary to obtain sufficient and reliable evidence of conformity.

3. When assessing whether remote techniques are appropriate, the notified body shall take into account at least:

   (a) the nature, complexity and risks of the product;

   (b) the nature of the conformity assessment activity and the requirements to be verified;

   (c) whether physical inspection, sampling, testing, measurement or direct observation is necessary;

   (d) the results of previous conformity assessments and any relevant non-compliance, complaint, accident or corrective action;

   (e) whether the identity, location and condition of the product, site, process and evidence can be reliably verified; and

   (f) the suitability and security of the information and communication technologies used, including the protection of confidential information, trade secrets and personal data.

4. The notified body shall retain full responsibility for and control over the conformity assessment activities performed remotely. It shall ensure that:

   (a) those activities are carried out by competent personnel in accordance with a documented assessment plan;

   (b) sufficient, objective and verifiable evidence is obtained;

   (c) the remote activity is interrupted and an on-site assessment is carried out where sufficient evidence cannot be obtained or the conditions for the use of remote techniques are no longer fulfilled; and

   (d) the use of remote assessment is compatible with the requirements of the notification for the applicable scope.

5. The notified body shall document the reasons for using remote techniques, the activities performed remotely, the evidence obtained, any limitations encountered and any on-site or other follow-up activities required.

   The notified body may not have recourse to remote techniques under the following circumstances:

   (a) when the assessment is the initial evaluation of a conformity assessment body in a specific area;

(b) when it is not possible to meet the specific legislative requirements of the requirements of the applicable scheme;

(c) when there is inadequate connectivity;

(d) when some sectors and situations are restricted by the sensory limits of remote techniques (need to hear, smell, feel, have a not limited view), including witnessing of activities;

(e) when privacy and security concerns or limitations of equipment exist.

6. The applicable aligned Union product legislation may specify the activities for which remote techniques may or may not be used and may lay down additional conditions, limitations or safeguards.

Article 41

Personnel of the notified body

1. The notified body shall have at its disposal at all times a sufficient minimum number of staff members, possessing the competence corresponding to the scope and conditions of under which it has been notified.

2. The sufficient minimum number of staff members referred to in paragraph 1, shall be employed by the notified body on a permanent basis and integrated into the organisational structure of the notified body in the Member State in which the notified body is established.

3. The sufficient minimum number of staff members shall act under the direct responsibility and authority of the notified body and the notified body shall be fully responsible and in control of the tasks they perform.

Article 42

Competence of the personnel of the notified body

1. The notified body shall define, document and apply role-specific competence criteria for all personnel, including, where relevant, external experts, performing evaluation, review and decision-making functions related to conformity assessment activities for which it has been notified.

2. Such competence criteria referred to in paragraph 1 shall ensure that personnel have sound technical and vocational training covering all conformity assessment activities assigned to the notified body, as well as appropriate qualifications, experience and up-to-date knowledge of relevant technologies, applicable harmonised standards, harmonised standardisation deliverables, common specifications and other relevant technical specifications, and the relevant provisions of Union harmonisation legislation and its implementing acts.

3. 3. Each notified body shall ensure that its personnel

4. a) has satisfactory knowledge of the requirements of the conformity assessment activities they carry out and is granted the appropriate authority to perform those activities in accordance with the notified body’s procedures;

5. b) has the ability to prepare and complete certificates, records and reports demonstrating that conformity assessment activities have been carried out in accordance with applicable requirements.

6. c) receives appropriate initial and ongoing training and professional development to ensure the continued validity of their competence and up-to-date knowledge of relevant technologies and regulatory requirements.

7. 4. The notified body shall maintain records of competence and shall monitor and periodically review the competence of its personnel.

Article 43

Authorisation and assignment of personnel

1. The notified body shall establish and implement procedures for the designation and assignment of personnel, including, where relevant, external experts, to specific conformity assessment activities.

2. The authorisation referred to in paragraph 1 shall be granted only on the basis of demonstrated competence and shall be limited to the specific evaluation, review and decision-making functions for which the personnel have been assessed as competent.

3. The notified body shall ensure that only authorised personnel perform conformity assessment activities and that the assignment of personnel ensures appropriate separation between evaluation, review and decision-making functions.

4. No conformity assessment shall be carried out exclusively by external experts. Where external experts are involved in an assessment, the final decision shall be taken by personnel employed by the notified body.

5. Applicants shall be informed in advance of the involvement of external experts and shall have the right to object to their participation in the assessment of their application.

6. External experts shall immediately recuse themselves where they identify an actual or potential conflict of interest.

7. Records of personnel authorisations, including their scope, validity and any limitations, shall be maintained by the notified body and shall be reviewed periodically.

Article 44

Liability of notified bodies

The notified body shall have adequate arrangements to cover liabilities arising from its conformity assessment activities, including the taking out of appropriate liability insurance, unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

Article 45

Confidentiality and information handling

1. The notified body shall ensure confidentiality of all information obtained during conformity assessment, except where disclosure is required by Union or national law.

2. The personnel of the notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation or other Union or national law, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

3. The notified body shall maintain safe and secure record-keeping systems storing impartiality records, conflict-of-interest declarations, subcontractor evaluations, competence files and decision documentation.

4. The notified body shall ensure that all information referred to in this Article remain readily accessible to the notified body and can be made available without undue delay to the notifying authority and other competent authorities upon request.

5. Upon request, the notified body shall provide, without being bound by professional secrecy, the market surveillance authority with all documentation and information necessary to verify the conformity assessment it has carried out, including technical evidence, evaluation records, review reports, decision justifications, subcontractor reports and any relevant correspondence.

Article 46

Documentation and transparency

1. The notified body shall maintain sufficient documented information and records to demonstrate compliance with the applicable requirements, including those relating to impartiality, competence, independence, authorisation and assignment of personnel, and control of subcontractors and external experts. Such documented information and records shall ensure transparency, traceability and reproducibility of conformity assessment activities and decisions.

2. Upon request, the notified body shall make available to the notifying authority relevant documented information and records, including, as applicable:

   (a) records of impartiality risk analyses and controls;

   (b) records of the impartiality safeguarding mechanism, including minutes and conclusions;

   (c) competence, training and authorisation records of personnel and external experts;

   (d) assessments and controls of subcontractors;

   (e) records demonstrating the basis and process of conformity assessment decisions, without prejudice to the protection of confidential and commercially sensitive information.

3. Notified bodies shall participate in the relevant notified body coordination group established under the applicable Union harmonisation legislation. Exceptional absences shall be duly justified and documented.

4. Notified bodies shall participate in relevant standardisation activities or shall ensure that relevant personnel are kept informed of the outcomes of such activities. The notified body shall take into account and apply, as general guidance, the administrative decisions, recommendations and documents resulting from the work of the notified body coordination group, and, where relevant, standardisation activities, in a consistent manner.

Article 47

Operational obligations of notified bodies

1. Notified bodies shall carry out the conformity assessment activities provided for in the respective Union product legislation listed in Annex I in an adequate and proportionate manner, thus avoiding unnecessary burdens for economic operators. They shall perform their activities in accordance with this Regulation taking due account of the size of the undertaking whose products they examine, the sector in which it operates, its structure, the degree of complexity of the technology of the products in question and the mass or serial nature of the production process.

2. When performing their activities, the notified bodies shall respect the degree of rigour and the level of protection required for the compliance of the product with a Union product legislation.

3. Where a notified body finds that the product does not meet the relevant and applicable essential or other substantive requirements safety requirements laid down by the respective Union product legislation, the requirements in corresponding harmonised standards or harmonised standardisation deliverables, where such harmonised standards or harmonised standardisation deliverables are applied, or the requirements in corresponding common specifications, where such specifications are applied, it shall require the manufacturer to take appropriate corrective measures and shall not issue an EU-type examination certificate.

4. Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate, a notified body finds that a product no longer complies with the applicable essential or other substantive requirements, it shall require the manufacturer to take appropriate corrective measures, and shall suspend or withdraw the EU-type examination certificate if necessary.

5. Where the corrective measures referred to in paragraph 4 are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EU-type examination certificates, as appropriate

6. Where a notified body is informed by a market surveillance authority that a product for which the notified body has issued an EU-type examination certificate does not comply with the essential or other substantive requirements safety requirements laid down by the respective Union product legislation, it shall withdraw the EU-type examination certificate in respect of that product.

Article 48

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 that they have issued;

   (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 the respective Union product legislation 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 49

Coordination of notified bodies

1. The Commission shall ensure appropriate coordination and cooperation between notified bodies operating through:

   (a) in the form of sectoral coordination groups of notified bodies in the form established under the respective Union harmonisation legislation; and

   (b) a plenary coordination group established under this Regulation.

2. The respective groups shall meet on a regular basis and at least annually.

3. The bodies notified under the respective Union harmonisation legislation shall participate in the work of the respective groups.

4. The Commission may establish the specific arrangements for the functioning of the coordination groups of notified bodies.

Chapter 5
ACCREDITATION

Article 50

Scope

1. Accreditation of a conformity assessment body to carry out a specific conformity assessment activity shall be based on harmonised standards, harmonised standardisation deliverables and common specifications and, where applicable, any additional requirements, including those set out in the relevant Union product legislation or relevant sectoral schemes.

2. Articles 52 to 56 shall apply only to the accreditation of conformity assessment bodies, and irrespective of the legal status of the body performing the accreditation.

Article 51

General principles

1. Each Member State shall appoint a sole national accreditation body. The national accreditation body shall, subject to Article 55, be the only body entitled to provide accreditation services in the Member State where it is established.

2. Where a Member State considers that it is not economically meaningful or sustainable to have a national accreditation body or to provide certain accreditation services, it shall, as far as possible, have recourse to the national accreditation body of another Member State.

3. A Member State shall inform the Commission and the other Member States where it has recourse in accordance with paragraph 2 is to the national accreditation body of another Member State.

4. On the basis of the information referred to in paragraph 3 of this Article and Article 59, the Commission shall draw up, make publicly available and keep up to date a list of national accreditation bodies.

5. Where accreditation is not operated directly by public authorities, a Member State shall entrust its national accreditation body with the operation of accreditation as a public authority activity and grant it formal recognition.

6. The responsibilities and tasks of the national accreditation body shall be clearly distinguished from those of other national authorities.

7. The national accreditation body shall operate on a not-for-profit basis.

8. The national accreditation body shall not offer or provide any activities or services that conformity assessment bodies provide, nor shall it provide consultancy services, own shares in, or otherwise have a financial or managerial interest in, a conformity assessment body. It shall ensure that its personnel and any other persons participating in its activities do not perform tasks or participate in decisions in situations involving an actual or potential conflict of interest.

9. Each Member State shall ensure that its national accreditation body has the adequate financial and human resources for the proper performance of its tasks, including the fulfilment of special tasks, such as activities for within the context of the European accreditation infrastructure pursuant to Article 61 and international accreditation cooperation and activities that are required to support public policy and which are not self-financing.

10. The national accreditation body shall be a member of the body recognised under Article 61.

11. National accreditation bodies shall establish and maintain appropriate structures to ensure the effective and balanced involvement of all interested parties within their organisations. They shall participate in the structures established for that purpose by the body recognised under Article 61.

Article 52

Request for accreditation

1. National accreditation bodies shall provide public access to up-to-date information about the conformity assessment activities for which they provide accreditation.

2. Within 15 working days of receipt of a request for accreditation submitted by a conformity assessment body, the national accreditation body shall inform that conformity assessment body whether it accepts the request for assessment.

3. Where the national accreditation body does not accept the request, it shall provide the reasons for its decision. Where the request is not accepted because the national accreditation body does not provide accreditation for the conformity assessment activities concerned, it shall inform the conformity assessment body of any national accreditation bodies whose accreditation activities cover those conformity assessment activities, based on the list referred to in Article 61(5), and of the conditions under which accreditation may be requested from another national accreditation body pursuant to Article 55.

4. Where the national accreditation body accepts the request for assessment, it shall inform the conformity assessment body, within the period referred to in paragraph 2,

whether the documentation submitted is sufficient or needs to be supplemented. It shall also indicate the expected starting date of the assessment, the applicable procedural time limits and the expected date of completion of the accreditation procedure. After the successful completion of the assessment, the national accreditation body shall issue the relevant accreditation certificate without undue delay and, in any event, no later than one month after the adoption of the decision attesting the competence of the conformity assessment body.

5. Where the start or completion of the assessment is delayed, the national accreditation body shall inform the conformity assessment body, before the relevant expected date, of the reasons for the delay and of the revised expected starting or completion date. Where the conformity assessment body does not accept the delay, it may withdraw its request for accreditation. In such cases, the national accreditation body shall return any original documents submitted by the conformity assessment body and reimburse any fees paid for assessment activities that have not been carried out.

Article 53

Operation of accreditation

1. A national accreditation body shall, when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to that effect.

2. Where the applicable Union harmonisation legislation permits the competence of conformity assessment bodies to be demonstrated otherwise than through accreditation and a Member State decides not to use accreditation, that Member State shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects to carry out conformity assessment activities under that legislation.

3. National accreditation bodies shall monitor the conformity assessment bodies to which they have issued an accreditation certificate.

4. Where a national accreditation body ascertains that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific activity or has committed a serious breach of its obligations, that accreditation body shall, having regard to the seriousness, extent and duration of the failure, take all appropriate measures without undue delay to restrict, suspend or withdraw the accreditation certificate.

5. Member States shall establish procedures for the resolution of appeals, including, where appropriate, legal remedies, against accreditation decisions a failure to adopt such decisions within the applicable time limits.

Article 54

Principle of non-competition

1. National accreditation bodies shall not compete with conformity assessment bodies.

2. National accreditation bodies shall not compete with other national accreditation bodies.

3. National accreditation bodies shall be permitted to operate across national borders, within the territory of another Member State, either at the request of a conformity assessment body in the circumstances set out in Article 55(2), or, where they are asked to do so by a national accreditation body in accordance with Article 55(4), in cooperation with the national accreditation body of that Member State.

Article 55

Cross-border accreditation

1. Where a conformity assessment body requests accreditation, it shall do so with the national accreditation body of the Member State in which it is established or with the national accreditation body to which that Member State has had recourse in accordance with Article 51(2).

2. A conformity assessment body may request accreditation from a national accreditation body other than those referred to in the paragraph 1 in any one of the following situations:

   (a) where the Member State in which it is established has decided not to establish a national accreditation body and has not had recourse to the national accreditation body of another Member State in accordance with Article 51(2);

   (b) where the national accreditation bodies referred to in the first paragraph do not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;

   (c) where the national accreditation bodies referred to in paragraph 1 have not successfully undergone peer evaluation under Article 58 in respect of the conformity assessment activities for which accreditation is sought;

   (d) where the national accreditation bodies referred to in paragraph 1 have not explicitly accepted a request for accreditation submitted by a conformity assessment body within the period referred to in Article 52(2);

   (e) where the national accreditation bodies referred to in paragraph 1 have accepted the request for accreditation submitted by a conformity assessment body but have failed, without duly justified reasons, to start or complete the accreditation procedure within the time limits communicated pursuant to Article 52(4) or, where applicable, the revised time limits communicated pursuant to Article 52(5).

3. Where a national accreditation body receives a request pursuant to paragraph 2, it shall treat the conformity assessment body concerned in the same manner as it would treat a conformity assessment body established in the same Member State as that in which the national accreditation body is established.

4. Where a national accreditation body receives a request pursuant to paragraph 2, point (b), paragraph 2, point (c), paragraph 2, point (d) or paragraph 2, point (e), it shall verify that the relevant condition laid down in that point is fulfilled and inform the national accreditation body of the Member State in which the requesting conformity assessment body is established before accepting the request. In such cases, the national accreditation body of the Member State in which the requesting conformity assessment body is established may participate as an observer.

5. A national accreditation body may request another national accreditation body to carry out part of the assessment activity. In such a case, the requesting national accreditation body shall remain responsible for the assessment and for the accreditation decision and shall issue the accreditation certificate.

Article 56

Requirements for national accreditation bodies

A national accreditation body shall fulfil the following requirements. It shall:

(a) be organised in such a manner as to ensure that it is independent of the conformity assessment bodies it assesses and of commercial pressures, and to ensure that no conflicts of interest with conformity assessment bodies occur;

(b) be organised and operated so as to safeguard the objectivity and impartiality of its activities;

(c) require all personnel and members of committees participating in the accreditation activities to disclose any actual or potential conflict of interest as soon as it arises or becomes known to them, and shall establish appropriate procedures for assessing and managing such conflicts, including, where necessary, the exclusion of the person concerned from the relevant activities or decisions;

(d) ensure that, for a period of at least three years after ceasing to hold a governance or decision-making role in a conformity assessment body or in an association representing conformity assessment bodies, the person concerned does not participate in the governance or accreditation decisions of the national accreditation body where that previous role could give rise to an actual or potential conflict of interest or otherwise compromise impartiality;

(e) ensure that each decision relating to the attestation of competence is taken by competent persons different from those who carried out the assessment;

(f) have adequate arrangements to safeguard the confidentiality of the information obtained;

(g) identify the activities for which it is competent to perform accreditation, referring, where appropriate, to relevant Union or national legislation, accreditations schemes and standards;

(h) set up the procedures necessary to ensure efficient management and appropriate internal controls;

(i) have sufficient competent personnel at its disposal for the proper performance of its tasks;

(j) document the duties, responsibilities and authorities of personnel who could affect the quality of the assessment and of the attestation of competence;

(k) establish, implement and maintain procedures for monitoring the performance and competence of the personnel involved;

(l) verify, when assessing and monitoring conformity assessment bodies, that conformity assessments are carried out in an appropriate manner, in particular that unnecessary burdens are not imposed on undertakings and that due account is taken 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;

(m) publish audited annual accounts prepared in accordance with generally accepted accounting principles.

Article 57

Compliance with requirements for national accreditation bodies

1. Where a national accreditation body does not comply with its obligations and the requirements laid down in this Regulation, the Member State concerned shall take appropriate corrective action or shall, without undue delay, ensure that such corrective action is taken, and shall inform the Commission thereof.

2. Member States shall monitor their national accreditation bodies at regular intervals, and, in addition, whenever information giving rise to reasonable doubts as to a national accreditation body's compliance is brought to their attention, in order to ensure that they fulfil the requirements laid down in Article 56 on a continuing basis.

3. Member States shall take the utmost account of the results of peer evaluation under Article 66 when carrying out the monitoring referred to in paragraph 2.

4. National accreditation bodies shall have in place the necessary procedures to receive, investigate and resolve complaints against the conformity assessment bodies they have accredited, and shall take appropriate action where such complaints are substantiated.

Article 58

Peer evaluation

1. National accreditation bodies shall undergo peer evaluation organised by the body recognised in accordance with Article 61.

2. Stakeholders shall have the right to participate in the system set up for the supervision of peer evaluation activities, but not in individual peer evaluation procedures.

3. Member States shall ensure that their national accreditation bodies regularly undergo peer evaluation as required by paragraph 1.

4. Peer evaluation shall be operated on the basis of sound and transparent evaluation criteria and procedures, in particular concerning structural, human resource and process requirements, confidentiality and complaints. Appropriate procedures for the review of peer-evaluation findings and outcomes shall be provided for as part of the system set up for the supervision of peer evaluation activities referred to in paragraph 2.

5. Peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 56, taking into account the relevant harmonised standards, harmonised standardisation deliverables or common specifications referred to in Article 8.

6. The outcome of peer evaluation shall be published and communicated by the body recognised in accordance with Article 61 to all Member States and the Commission.

7. The Commission shall, in cooperation with the Member States, oversee the rules and the proper functioning of the peer evaluation system.

Article 59

Information obligation

1. Each national accreditation body shall inform the other national accreditation bodies, and the body recognised under Article 61, of the activities in respect of which it operates accreditation and of any changes thereto.

2. Each Member State shall inform the Commission and the body recognised under Article 61 of the identity of its national accreditation body and of all activities in respect of which that body operates accreditation in support of Union harmonisation legislation, and of any changes thereto.

3. Each national accreditation body shall make publicly available and keep up to date the information concerning the results of its peer evaluation, the activities in respect of which it operates accreditation and any changes thereto.

Article 60

Requests to the body recognised in accordance with Article 61

1. The Commission may request the body recognised in accordance with Article 61 to contribute to the development, maintenance and implementation of accreditation in the Union.

2. When requesting the development of, or approving or recognising sectoral schemes, the Commission shall ensure that those schemes identify the technical specifications necessary to meet the level of competence required by Union harmonisation legislation in fields with specific requirements relating to technology, health and safety, environmental protection or any other related requirements or any other aspect of public interest protection.

3. For the purposes of paragraph 2, the Commission may, in particular:

   (a) request the body recognised in accordance with Article 61 to lay down evaluation criteria and procedures for peer evaluation and to develop sectoral accreditation schemes;

   (b) approve or recognise for use within the European accreditation infrastructure any existing scheme that already lays down evaluation criteria and procedures for peer evaluation.

Article 61

European accreditation infrastructure

1. The European co-operation for Accreditation, recognised pursuant to Article 14 of Regulation (EC) No 765/2008, shall continue to be recognised as the body responsible for the European accreditation infrastructure under this Regulation. It shall fulfil the requirements laid down in Annex V.

2. The agreement concluded between the Commission and the European co-operation for Accreditation pursuant to Article 14(2) of Regulation (EC) No 765/2008 and in force on the date of application of this Regulation shall continue to apply until it is amended, replaced or terminated. Where necessary, the Commission and the European co-operation for Accreditation shall amend or replace that agreement in order to ensure its conformity with this Regulation.

That agreement shall specify, inter alia, the detailed tasks of the body, funding provisions and provisions for its supervision. Both the Commission and the body shall be able to terminate the agreement without cause subject to a reasonable period of notice specified in the agreement.

3. The Commission and the body shall make the agreement public.

4. The Commission shall inform the Member States and national accreditation bodies of any amendment, replacement or termination of the agreement referred to in paragraph 2 and of any decision taken pursuant to paragraph 6.

5. Only one body may be recognised at any given time as the body responsible for the European accreditation infrastructure.

6. Where the Commission considers that the European co-operation for Accreditation no longer fulfils the requirements laid down in Annex V or the obligations arising from the agreement referred to in paragraph 2, it shall request that body to take the necessary corrective action within an appropriate period.

Where the body fails to take the necessary corrective action within that period, or where the agreement referred to in paragraph 2 has been terminated, the Commission may, after consulting the Member States, withdraw its recognition and recognise another body which fulfils the requirements laid down in Annex V.

The Commission shall take the measures necessary to ensure the continuity of the European accreditation infrastructure. Except where imperative grounds of urgency require otherwise, the withdrawal of the recognition of the existing body and the recognition of another body shall take effect simultaneously.

The Commission shall adopt the decisions referred to in the second subparagraph by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 136(3).

7. The body recognised in accordance with paragraph 1 shall establish, publish and keep up to date a list of the conformity assessment activities for which each national accreditation body provides accreditation, on the basis of information supplied by those national accreditation bodies.

8. The list shall identify, for each national accreditation body, the conformity assessment activities concerned and, where applicable, the relevant Union harmonisation legislation, accreditation scheme or standard, and shall include a reference to the public information made available by the national accreditation body concerned.

9. National accreditation bodies shall provide the body recognised in accordance with paragraph 1 or, where applicable, paragraph 5 with the information necessary for that purpose and shall inform it without undue delay of any change to that information.

Article 62

Status of a body pursuing a Union policy objective

The body recognised under Article 61 shall be considered a body having an objective forming part and supporting a Union policy within the meaning of Article 183 of Commission Regulation (EC, Euratom) No 2024/2509.

Article 63

Financing arrangements

The production and revision of sectoral accreditation schemes referred to in Article 60(2), point (a) and the activities of the secretariat of the body recognised under Article 61 shall be remunerated and may be financed by the Union in accordance with Article 129(1).

TITLE IV

DIGITAL PRODUCT PASSPORT FRAMEWORK

Chapter 1
DIGITAL PRODUCT PASSPORT

Article 64

Application of the digital product passport

1. This Chapter establishes the common horizontal framework governing digital product passports. It shall apply where a digital product passport is required pursuant to Union law laying down product-specific or other requirements, without prejudice to any additional or more specific requirements laid down in that Union law.

2. The digital product passport referred to in paragraph 1 shall be created, registered, processed, made accessible, updated, stored and maintained in accordance with this Chapter.

3. Where more than one act of Union law requires a digital product passport for the same product, the product shall be covered by a single digital product passport containing all information required under those acts.

4. That digital product passport shall be accessible through a data carrier and shall be linked to a single unique product identifier. It shall be established at the most granular level required by Union legislation in accordance with Article 68.

Article 65

Minimum content of the digital product passport

1. The following elements shall, as a minimum, be defined in the digital product passport:

   (a) identify the products or product groups that are to be requiring a digital product passport;

   (b) require the inclusion of product-specific data and the level of granularity for which the data needs to be provided;

   (c) specify the legal effects attached to the inclusion of specific information in the digital product passport;

   (d) require that the digital product passport be established at model, batch or item level;

   (e) require that the access to the digital product passport be provided by means of a single data carrier or, where duly justified, by means of more than one data carrier;

   (f) establish the period for which the digital product passport shall remain available;

   (g) specify the access rights for end users, manufacturers, authorised representative, importers, distributors, dealers, professional repairers, independent operators, refurbishers, remanufacturers, recyclers, market surveillance authorities and

customs authorities, civil society organisations, trade unions and other relevant actors for the digital product passport data, including the Commission;

(h) specify the respective access rights and the data to be included in the reference digital product passport for the purposes of Article 77, and the conditions under which such reference digital product passport may deviate from the digital product passport, provided that any such deviation is limited to what is strictly necessary, does not mislead end-users, and is clearly identified as referential;

(i) specify the respective access rights and the data to be included in the pre-manufacture digital product passport for the purposes of Article 78, and the conditions under which such digital product passport for unfinished products may deviate from the digital product passport, provided that any such deviation is limited to what is strictly necessary, does not mislead end-users, and is clearly identified as pre-manufacture digital product passport.

2. The following additional or more specific elements may be defined in the digital product passport:

(a) where justified and appropriate, specify the events occurring after the placing on the market or putting into service of a product, that shall require the responsible economic operator or other responsible actors to update, or ensure the updating of, the information contained in the digital product passport, and may further specify the responsibility for the updated information;

(b) specify additional post-market events requiring the creation and registration of a new digital product passport in accordance with Article 70(2);

(c) provide that economic operator responsible for creating the digital product passport may, on a voluntary basis, establish a digital product passport at a level of granularity more detailed than that required under such Union law, and is required to determine the conditions under which such digital product passport may be established;

(d) specify additional optional data which can be provided by the economic operators and the option to add voluntary data in the digital product passport;

(e) specify the back-up requirements applicable to the digital product passport in accordance with Article 75; and

(f) for products consisting of one or more components which are subject to DPP requirements, provide for a derogation from the obligation laid down in Article 69(1).

3. The provisions set out in paragraph 1 and paragraph 2 shall support the effective implementation of the digital product passport in a balanced and proportionate manner, while taking due account of the product life cycle, the interoperability of the system's technical architecture, and the costs associated with these obligations.

Article 66

Creation, registration, content, lifecycle and legal effects of the digital product passport

1. Before a product subject to a digital product passport under Union law is placed on the market or put into service, the economic operator required under Union law to create the digital product passport shall create and register in the registry the data required

under Union law, including the unique product identifier, the unique operator identifier and, where relevant, the unique facility identifier.

2. The digital product passport shall:

(a) correspond to a specific model, batch or item as defined by the applicable Union law;

(b) contain at least the data required under the applicable Union law;

(c) be accurate, truthful, complete and up to date;

(d) be available in the language or languages required by the Member State in which the product is made available on the market or put into service;

(e) be accessible to the actors referred to in Article 72(3), in accordance with their respective access rights under the applicable Union law;

(f) remain available for the period specified in the applicable Union law, or where no period is specified, for at least 10 years after the last unit of the model is placed on the market, unless otherwise set out in a relevant Union law;

(g) remain available, where a back-up is required in accordance with Article 75, for the period specified in the applicable Union law, including where the economic operator responsible for its creation is no longer able to maintain, update or provide access to it;

(h) the data carrier shall be physically present on the product, its packaging or in the documentation accompanying the product in accordance with the applicable Union law and connected to a persistent unique product identifier; and

(i) fulfil the specific and technical requirements laid down in this Chapter and in delegated or implementing acts adopted pursuant to it or other appropriate Union law.

3. The economic operator responsible for creating the digital product passport shall assume the responsibility for the information contained in the digital product passport and ensure it is accurate, complete and up to date and consistent with the technical requirements under Union law.

4. Where other Union law requires information relating to a product to be made available by means of a data carrier but does not specify the digital product passport, that information shall nevertheless be made accessible through the data carrier of the digital product passport. That data carrier shall constitute the single point of access to the information required under this Regulation and other Union law.

5. The economic operator responsible for creating the digital product passport shall ensure that a link to the section of the Safety Gate Portal referred to in Article 34(3) of Regulation (EU) 2023/988 enabling end users to inform the Commission of products that might present a risk to the health and safety or fundamental rights of end users displayed when accessing the digital product passport.

6. A digital product passport shall be considered valid only where:

(a) it has been created in accordance with the requirements set out in this Chapter and any other applicable requirements under Union law relating to the creation of the digital product passport;

(b) it has been duly registered in the registry referred to in Article 81; and

(c) it has not been invalidated in the registry by a market surveillance authority, customs authority or other public authorities in accordance with their respective powers under Union law.

Article 67

Visual identity of the digital product passport

1. To ensure that the digital product passport is easily recognisable and to promote its effective and efficient use by end users, economic operators, competent national authorities and customs authorities, or other relevant actors, the digital product passport shall have a visual identity consisting, at a minimum, of:

   (a) the digital product passport logo;

   (b) the additional elements to be displayed on, or accompanying, the data carrier; and

   (c) the elements of the digital product passport user interface.

2. The acronym "DPP" shall be used as the common Union acronym of the digital product passport.

3. The visual identity of the digital product passport and the data carrier through which the digital product passport is accessible shall be affixed to the product. Where, due to the size or nature of the product, the visual identity and the data carrier cannot be affixed to the product, they shall be affixed to the packaging, if any, or included in the documentation accompanying the product, as specified in the applicable Union law. The visual identity and the data carrier shall be clearly visible and accessible to end users before purchase and to market surveillance authorities.

4. The data carrier shall, where relevant for the products concerned, comply with the relevant harmonised standards, harmonised standardisation deliverable or common specifications the reference of which have been published in the *Official Journal of the European Union*.

5. Where the product is offered for sale online or through other means of distance sales, the visual identity of the web-link through which the digital product passport is directly accessible shall be clearly and visibly displayed in the offer.

6. Where Union legislation permits the inclusion in the digital product passport of optional or voluntary information pursuant to Article 64(6), point (f), that information shall comply with the visual identity as laid down in paragraph 1. It shall be clearly distinguishable from the information required under Union law and shall not impair its visibility, accessibility or reliability.

7. The economic operator placing product on the market or putting it into service shall not use any visual identity that imitates the visual identity of the digital product passport as laid down in paragraph 1 in a manner liable to mislead end users.

8. The Commission shall adopt, by means of an implementing act adopted in accordance with the examination procedure referred to in Article 136(3), the rules on the visual identity of the digital product passport, including the elements to be displayed in the data carrier and the manner in which the digital product passport content and structure is to be presented to end-users.

Article 68

Granularity of the digital product passport and product traceability

1. Where, under Union law, a product is subject to more than one obligation to establish a digital product passport, the responsible economic operator shall establish one single digital product passport at the most granular level required by those obligations.

2. The responsible economic operator shall ensure that the digital product passport will enable the traceability of the product at different levels of granularity by:

   (a) where, pursuant to applicable Union law, the digital product passport is created at item level, the economic operator responsible for creating the digital product passport shall link both the batch identifier and the model identifier to that digital product passport when it is registered in the registry referred to in Article 81, where a batch or a model exists for the product; or

   (b) where, pursuant to other applicable Union law, the digital product passport is created at batch level, the economic operator responsible for creating the digital product passport shall link the model identifier to that digital product passport when it is registered in the registry referred to in Article 81, where a model exists for the product.

3. The identifiers listed in paragraph 2 shall enable the European Commission, market surveillance authorities, customs authorities and other actors, in accordance with their respective access rights and tasks under the applicable Union law, to identify the batch and the model to which an item or batch belongs, including for the purpose of identifying, comparing and controlling all products from model to item level.

Article 69

Digital product passport for products incorporating components subject to a digital product passport

1. Where a product consists of, or contains, one or more components in respect of which a digital product passport is required under Union law, the economic operator registering the digital product passport for that product shall ensure that the digital product passport of that product enables the identification of, and access to, the digital product passports required for those components through a digital link.

2. For the purposes of paragraph 1, the digital product passport of the product shall include, for each component required to have a digital product passport, at least the unique product identifier of that digital product passport and other relevant data as set out under relevant Union legislation.

3. The access rights to the data mandated in paragraph 1 and paragraph 2 shall be set in the relevant applicable Union law.

4. Where the level of granularity applicable to a component differs from the level of granularity applicable to the product in which that component is incorporated, the digital product passport of the product shall contain, or provide access to, the information necessary to establish a reliable link between the product and the component at the more granular level, insofar as this is necessary to identify the specific component, batch or item incorporated.

5. The digital product passport of the product shall not be required to reproduce data contained in the digital product passport of an incorporated component, provided that those data remain accessible through the digital link referred to in paragraph 1.

6. Where following a concluded market surveillance investigation the digital product passport of a component incorporated in a product subject to a digital product passport is deemed invalid, the digital product passport of the product will be deemed invalid as well.

Article 70

Post-market updates of the digital product passport

1. Where Union law requires that information on an event occurring after a product has been placed on the market or put into service be included in the digital product passport, that information shall be added to the digital product passport without undue delay.

2. The information referred to in paragraph 1 shall be entered by the economic operator responsible under the applicable Union law for carrying out the relevant event, or for ensuring that information concerning that event is entered in the digital product passport.

3. Before entering that information, the economic operator referred to in paragraph 4 shall be registered and verified in the registry and shall obtain the digital credentials necessary to exercise the applicable access and updating rights. Those rights shall enable that economic operator to enter information only in the section or data fields designated for the relevant event and, where necessary, to read restricted information contained in the digital product passport only to the extent necessary for that purpose.

4. Union law requiring information concerning a post-market event to be included in the digital product passport shall specify at least:

   (a) the event concerned;

   (b) the economic operator responsible for carrying out the event or for entering the related information in the digital product passport;

   (c) any requirements that must be fulfilled by that economic operator in order to perform that role;

   (d) the information and, where applicable, evidence to be entered in the digital product passport and the section or data fields of the digital product passport where this must be entered;

   (e) the data that will be updated or notified in the registry;

   (f) the applicable access and updating rights;

   (g) the level of granularity at which the information is to be recorded; and

   (h) where applicable technical means supporting machine to machine (or automated) data transfer.

5. A digital product passport established at model or batch level shall be amended only if a post-market event applies to all products covered by that passport.

6. The Commission is empowered to adopt delegated acts in accordance with Article 135 to supplement this Regulation by laying down rules concerning post-market changes to the digital product passport, including:

   (a) the categories of actors authorised to introduce, modify or update information contained in the digital product passport after the product has been placed on the market or put into service;

   (b) the conditions and procedures governing the interaction of those actors with the digital product passport registry, including the submission, recording, updating, versioning, verification and, where appropriate, validation of such changes;

   (c) the verification requirements applicable to post-market changes to the digital product passport.

7. Where an economic operator substantially modifies a product subject to a digital product passport, that economic operator shall create and register a new digital product passport for the modified product in accordance with Article 65. The new digital product passport shall be linked to the original digital product passport or passports.

8. Other Union law may specify additional post-market events requiring the creation and registration of a new digital product passport. In such cases, the economic operator responsible under that Union law shall create and register the new digital product passport in accordance with Article 66 and shall link it to the original digital product passport.

Article 71

Transfer, retention and deletion of digital product passport registration data

1. The economic operator responsible for creating the digital product passport may transfer the obligations relating to a registered digital product passport to a new economic operator or a new actor authorised under Union law to assume those obligations, where:

   (a) that new economic operator or that new actor authorised under Union law is registered and verified in the registry in accordance with Article 81 and has accepted the transfer;

   (b) the transfer is recorded in the registry, together with the date of the transfer;

   (c) where a back-up is required, the arrangements under Article 75 have been continued or replaced.

2. Following a successful transfer in accordance with paragraph 1, the new economic operator or that new actor authorised under Union law shall assume the obligations relating to the digital product passport from the date recorded in the registry.

3. Where Union law does not specify the period for which a digital product passport must remain available, the digital product passport registration data shall be deleted automatically from the registry 10 years after the last unit of the model is placed on the market. Where Union law specifies such a period, the retention and deletion of those data shall be aligned with the period for which the digital product passport must remain available.

4. Where a digital product passport is linked pursuant to Article 69 to the digital product passport of a product which is still required to remain available, the period referred to

in paragraph 3 shall be extended under the expiry of the period applicable to that product.

Article 72

Technical design and operation of the digital product passport

1. Digital product passports shall be interoperable with each other and with the registry as regards the technical, semantic and organisational aspects of end-to-end communication and data transfer.

2. Data included in the digital product passport shall be based on open standards, developed with an interoperable format, and shall be, as appropriate, machine-readable, structured, searchable and transferable through an open interoperable data exchange network without vendor lock-in.

3. End users, economic operators, competent national authorities, customs authorities, the Commission and other relevant actors identified by the applicable Union law shall have easy and free of charge access to the digital product passport on the basis of their respective access rights under this Regulation and other applicable Union law.

4. The digital product passport shall be stored by the economic operator responsible for its creation or by a digital product passport service provider, without prejudice to the back-up requirements laid down in Article 75.

5. Where a new digital product passport is created for a product that already has a digital product passport, the new digital product passport shall be linked to the original digital product passport, and the information necessary to establish the history of the passport shall remain accessible to the actors entitled to access it.

6. Where the digital product passport is stored pursuant to paragraph 4 or otherwise processed by a digital product passport service provider, that provider shall comply with the provisions set under Article 76.

7. The rights to read, introduce, modify or update data in the digital product passport shall be restricted on the basis of the applicable access rights.

8. Data authentication, reliability and integrity of the data of the digital product passport shall be ensured by the responsible economic operator.

9. Digital product passports shall be designed and operated so as to ensure a high level of security, privacy and resilience, including protection against fraud and other forms of unauthorised access, use or interference.

10. Personal data related to end users shall not be stored in the digital product passport unless their storage is required by Union harmonisation legislation, other Union law or the consumer or other end user has given explicit consent in compliance with Article 6 of Regulation (EU) 2016/679 of the European Parliament and of the Council.

11. Economic operators shall not track, analyse or use information concerning access to or use of the digital product passport except to the extent strictly necessary to provide or secure the digital product passport or to comply with Union law.

12. The Commission may adopt implementing acts setting out procedures and practical arrangements related to the issuing, verification, renewal, suspension and revocation of the digital credentials of economic operators and other relevant actors that have rights to access, introduce, modify or update data in the digital product passport. Those implementing acts may also provide for periodic and event-driven re-verification of

identity, authority to represent an economic operator and regulatory capacity. They shall be adopted in accordance with the examination procedure referred to in Article 136(3).

Article 73

Unique identifiers

1. The unique product identifier, the unique operator identifiers and the unique facility identifiers shall, where relevant for the products concerned, comply with the relevant harmonised standards, harmonised standardisation deliverables or common specifications.

   (a) Where no unique operator identifier is available for an actor to be identified in the digital product passport the economic operator that creates or updates that digital product passport shall request such an identifier for that actor and shall provide the actor with the full details of the identifier once issued.

   (b) Where no unique facility identifier is available for a location or building to be identified in the digital product passport, the economic operator that creates or updates that passport shall request such identifier for the actor responsible for that location or building and shall, once issued, provide that actor with the full details of the identifiers.

   (c) Before submitting the request for such identifiers, the economic operator shall confirm with the concerned actor that no such identifier has already been issued for that actor, location or building.

2. Where a product is subject to more than one obligation to have a digital product passport under Union law, the same unique product identifier, unique operator identifiers, unique facility identifiers, where applicable, and unique registration identifier shall be used for the purposes of those obligations.

3. The Commission is empowered to adopt delegated acts in accordance with Article 135 to establish rules and procedures for the life cycle management of unique identifiers and of data carriers. In particular, those delegated acts shall establish rules for creating unique identifiers and data carriers for economic operators and digital product passport service providers.

4. The delegated acts adopted pursuant to paragraph 3 may set out rules:

   (a) ensuring that unique identifiers and data carriers are reliable, verifiable and globally unique;

   (b) on creating, assigning, maintaining, updating, suspending and withdrawing unique identifiers and data carriers;

   (c) on data management, interoperability and the prevention of duplicating identifiers.

5. When establishing the rules and procedures as referred to in paragraph 4, the Commission shall:

   (a) take into account relevant existing technical solutions and standards;

   (b) ensure that the rules and procedures established remain, to the greatest extent possible, technologically neutral.

Article 74

Common specifications for the digital product passport

The Commission may adopt implementing acts, where relevant, covering the essential or other substantive requirements for the digital product passport system following the procedure laid out in Article 32 of the New Standardisation Regulation.

Article 75

Back-up requirements for the digital product passport

1. Where applicable Union law lays down an obligation to ensure a back-up of a digital product passport, the economic operator required under Union law to create that passport shall ensure that such back-up is available through a digital product passport service provider for the period referred to in Article 66(2), point (g).

2. Union law laying down an obligation to provide a back-up pursuant to paragraph 1 shall specify whether the economic operator is required to provide an active or passive digital product passport back-up. For that purpose:

   (a) an active digital product passport back-up shall mean a continuously available and up-to-date back-up copy, made available through an independent third-party digital product passport service provider, in order to ensure access to the digital product passport for the period specified under the applicable Union law, including in cases of short-term technical unavailability and following insolvency, liquidation or cessation of activity in the Union; or

   (b) a passive digital product passport shall mean an up-to-date back-up copy, maintained by an independent third-party digital product passport service provider in cold storage and activated only following insolvency, liquidation or cessation of activity in the Union, so as to ensure access to the digital product passport for the period specified under the applicable law.

3. Where two or more Union legal acts applicable to the same digital product passport lay down different back-up requirements, the requirement ensuring the highest level of availability of the back-up shall apply. For the purposes of this paragraph:

   (a) a requirement to provide an active digital product passport back-up shall prevail over a requirement to provide a passive digital product passport back-up;

   (b) any requirement to provide a back-up shall prevail over the absence of such requirement, including where that absence results from a derogation or exception.

4. Where the applicable Union law requires a back-up the economic operator designated under Union law to create and upload the digital product passport shall include and keep up to date in the registry the link to the back-up copy and the reference to the digital product passport service provider entrusted with the back-up.

5. Union law may provide that no back-up shall be required where such a requirement would be disproportionate having regard to the characteristics of the product group concerned, the expected life of the product, the market circumstances and the size and role in the value chain of the economic operator concerned.

Article 76

Digital product passport service providers

1. Economic operators or other actors responsible under this Regulation or any other Union law responsible for the creation, storage or management of a digital product passport may delegate one or more of those tasks to a digital product passport service provider, unless the applicable Union law provides otherwise.

2. Economic operators or other actors responsible under this Regulation or any other Union law for registering the digital product passport in the registry referred to in Article 81 shall be entitled to have that registration carried out on their behalf by a digital product passport service provider.

3. Where a back-up is required, the digital product passport service provider shall be responsible for ensuring the hosting and continued availability of that back-up in accordance with Article 75. That responsibility shall subsist for the entire period during which the digital product passport is required to remain available, including after the insolvency, liquidation, cessation of activity within the Union of the economic operator responsible for creating the DPP.

4. Digital product passport service providers shall ensure that the responsible economic operator, when using the services of a digital product passport service provider, has the option for the digital product passport and, where relevant, the back-up of the digital product passport to be hosted within the Union.

5. A digital product passport service provider shall ensure the portability of digital product passports and related data, including any back-up copies, to the responsible economic operator or to another digital product passport service provider designated by that operator, in a structured, commonly used and machine-readable format, without undue delay and free of charge. The digital product passport service provider shall not impose contractual, technical or organisational obstacles to such portability. Chapter VI of Regulation (EU) 2023/2854 shall apply. Where the data concerned include personal data, Article 20 of Regulation (EU) 2016/679 shall apply.

6. A digital product passport service provider shall not sell, reuse or process the digital product passport data, in whole or in part, beyond what is necessary for the provision of the relevant storing or processing services, unless specifically agreed with the economic operator responsible for creating the digital product passport.

7. The delegation of tasks to service providers referred to in paragraph 1 or paragraph 2 shall not affect the responsibility of economic operators for compliance with their obligations under this Regulation or any other Union law mandating a digital product passport, including as regards the registration in the registry, the accuracy, completeness and availability of the information contained in the digital product passport.

8. The Commission may adopt delegated acts in accordance with the delegated act procedure laid down in Article 135 to supplement this Article by setting out the minimum technical, organisational and operational requirements that digital product passport service providers are to satisfy before commencing the provision of digital product passport services, insofar as necessary to ensure the secure, reliable, interoperable and continuous provision of those services,, and, where appropriate, a certification scheme to verify compliance with such requirements, and by setting out the requirements that those service providers are to comply with when providing digital product passport services. Those delegated acts may address, in particular,

synchronisation, recovery testing, portability, transfer between providers, activation of the back-up copy, termination of services and provider failure.

Article 77

Reference digital product passport

1. Where a digital product passport is required at item or batch level for a product offered for sale online or through other means of distance sales, and the specific product that will be supplied to a consumer and other end user and its associated digital product passport cannot be determined at the time of that offer, the responsible economic operator for creating the digital product passport shall make available a reference digital product passport for that product accessible to consumers and other end users, in a clear, easily visible and user-friendly manner.

2. The responsible economic operator shall ensure that:

   (a) the reference digital product passport referred to in paragraph 1 is clearly identified as a model-level set of data;

   (b) where information mandated in the digital product passport is already required at model level, that information shall be accurate and in compliance with the requirements under the applicable Union law in the reference digital product passport;

   (c) the information included in the reference digital product passport shall be consistent with the information contained in the digital product passport, and shall not include any misleading, promotional, advertising or otherwise unrelated information in accordance with Article 64;

   (d) the digital product passport shall make available a digital link to the reference digital product passport; and

   (e) the availability period of the reference digital product passport shall comply with the period the product is offered for distance sales.

3. The online marketplace shall ensure that:

   (a) the reference digital product passport is clearly displayed where such a reference digital product is required under Union law and labelled as provisional;

   (b) the reference digital product passport does not replace the digital product passport associated with the item or batch supplied, to which the end user is given access once that item or batch has been identified; and

   (c) end users are provided, without undue delay after the specific item or batch to be supplied has been identified and, in any event, before delivery, with access to the digital product passport for the product at the level of granularity required by Union law.

4. When a reference digital product passport is required under this Regulation or other Union law, the economic operator responsible for the creation of the digital product passport, or a third party acting on its behalf, shall register the reference digital product passport in the registry. For the purposes of registering a reference digital product passport, the economic operator responsible for the creation of the digital product passport, or the third party acting on its behalf, shall provide at least the following information:

(a) the digital link to the reference digital product passport;

(b) the unique product identifier of the reference digital product passport for the product or products covered by the related digital product passport; and

(c) any other data required under this Regulation or other Union law in accordance with Article 64.

5. The registry shall clearly indicate that the registration concerns a reference digital product passport and shall record its status as a reference digital product passport registration.

6. When a reference digital product passport is required under this Regulation or other Union law, the economic operator responsible for the creation of the digital product passport, or a third party acting on its behalf, shall ensure that the reference digital product passport is only made available until the digital product passport for the final product is known, and does not replace the obligation to provide access to the digital product passport.

Article 78

Pre-manufacture digital product passport

1. Where a digital product passport is required for a product that is offered for sale before it has been manufactured, and the data required in the digital product passport is not yet available, the economic operator responsible for creating the digital product passport shall make available a pre-manufacture digital product passport for that product accessible to consumers and other end users, in a clear, easily visible and user-friendly manner.

2. The responsible economic operator shall ensure that:

(a) a pre-manufacture digital product passport for a product referred to in paragraph 1 is clearly identified as provisional at the time the offer is made;

(b) where information d in the digital product passport is already required at model level, that information shall be accurate and in compliance with the requirements under the applicable Union law in the pre-manufacture digital product passport for unfinished products;

(c) the information included in a pre-manufacture digital product passport for a product that has not yet been manufactured shall be consistent with the information contained in the digital product passport created for the completed product, and shall not include any misleading, promotional, advertising or otherwise unrelated information in accordance with Article 64;

(d) the digital product passport shall make available a digital link to the pre-manufacture digital product passport; and

(e) the availability period of the pre-manufacture digital product passport shall comply with the period of the product is offered for sale.

3. In the event a pre-manufacture digital product passport is offered for distance sales, the provider of the online marketplace shall ensure that:

(a) the reference digital product passport is clearly displayed where such a reference digital product is required under Union law and labelled as provisional;

(b) the pre-manufacture digital product passport does not replace the digital product passport associated with the product supplied, to which the end user is given access once that product has been manufactured;

(c) end users are provided, without undue delay after the product has been manufactured, and in any event before delivery, with access to the digital product passport for the product at the level of granularity required by Union law.

4. When a pre-manufacture digital product passport is required under Union law, the economic operator responsible for the creation of the digital product passport, or a third party acting on its behalf, shall register the pre-manufacture digital product passport in the registry. For the purposes of registering a pre-manufacture digital product passport for unfinished products, the economic operator, or the third party acting on its behalf, shall provide at least the following information:

(a) the digital link of a pre-manufacture digital product passport;

(b) any other data required under this Regulation or other Union law in accordance with Article 64.

Once the digital product passport for the specific product is available, the economic operator responsible for the creation of the digital product passport, or the third party acting on its behalf shall ensure that a pre-manufacture digital product passport for a product that has not yet been manufacturer is linked to the corresponding digital product passport for that specific product in the registry.

5. The registry shall clearly indicate that the registration concerns a pre-manufacture digital product passport for unfinished products and shall record its status as a pre-manufacture registration.

Article 79

Assistance for micro-, small and medium-sized enterprises

No later than […]**,** the Commission shall provide assistance, in consultation with the competent national authorities, to micro-, small and medium-sized enterprises (SMEs) by providing them with guidelines on how to set up and operate a digital product passport for the relevant product, in accordance with this Regulation.

Article 80

Continuity of the existing digital product passport infrastructure and transitional provisions

1. From [date of application], the registry established pursuant to Article 13(1) of Regulation (EU) 2024/1781 shall constitute the registry referred to in Article 81 of this Regulation.

2. Unique identifiers, unique registration identifiers, data carriers, registry entries and digital credentials issued or created before [date of application] pursuant to Regulation (EU) 2024/1781 or other Union harmonisation legislation shall remain valid and shall not be required to be reissued or re-entered solely as a result of the application of this Regulation.

3. Digital product passports created before [date of application] in accordance with Regulation (EU) 2024/1781 or other Union harmonisation legislation shall remain valid for the period applicable to them, provided that they comply with the substantive

requirements applicable when they were created and can interoperate with the framework established by this Regulation.

4. Delegated and implementing acts adopted pursuant to Articles 10 to 13 of Regulation (EU) 2024/1781 before [date of application] shall remain in force until they are repealed or replaced by acts adopted pursuant to this Regulation. References in those acts to Regulation (EU) 2024/1781 shall, where appropriate, be construed as references to the corresponding provisions of this Regulation.

5. Existing approvals, certifications and contractual arrangements concerning digital product passport service providers shall remain valid until their expiry or replacement, subject to any transitional conditions laid down in delegated or implementing acts adopted pursuant to this Regulation.

Chapter 2
STORING IDENTIFIERS AND OTHER INFORMATION IN THE EUROPEAN PRODUCT ACT REGISTRY

Article 81

The European Product Act Registry

1. The Commission shall set up and manage the European Product Act Registry ('the registry'). The registry shall store in a secure manner at least the digital product passport registration data and the product responsibility record registration data, as mandated in Union law.

2. Before registering a digital product passport, a reference digital product passport, a pre-manufacture digital product passport, a product responsibility record or updating data related to them, an economic operator or other actor entitled under Union law to perform those actions shall register in the registry.

3. Registration of economic operators and other actors shall be completed only after the identity of the economic operator or other actor has been established and verified by electronic identification in accordance with Regulation (EU) No 910/2014; or by means of an electronic identification means that meets the requirements of Regulation (EU) No 910/2014 with regard to the assurance levels 'high', or an electronic attestation of attributes issued under Union law that enables the identification of the economic operator or other actor.

4. Before a product required to have a digital product passport is placed on the market or put into service, the economic operator required under Union law to create the digital product passport shall register in the registry at least:

   (a) the unique product identifier;

   (b) the relevant unique operator identifiers;

   (c) the unique facility identifier where appropriate;

   (d) for a product intended to be placed under the customs procedure 'release for free circulation', the commodity code shall also be uploaded;

   (e) any other data required under this Regulation or other Union law requiring a digital product passport.

5. Before a product subject to an obligation to have a product responsibility record is placed on the market or put into service, the economic operator required under Union law to create the product responsibility record shall register in the registry at least a valid product responsibility record containing at least the data necessary to identify that product, the responsible economic operator and other information as specified in Article 83 or other Union law.

6. The Commission shall ensure that the data stored in the registry are processed securely and in compliance with Union law, including applicable rules on the protection of personal data, cybersecurity, confidentiality and the protection of trade secrets.

7. In relation to its responsibility to set up and manage the registry and the processing of personal data resulting from that activity, the Commission shall be the controller within the meaning of Article 3, point (8), of Regulation (EU) 2018/1725.

8. Any processing of personal data carried out in the context of the Registry shall be conducted in full compliance with the applicable Union data protection framework, including Regulation (EU) 2016/679 and Regulation (EU) 2018/1725.

9. The Commission, customs authorities, market surveillance authorities and other competent national authorities shall have access to the registry for the purposes of carrying out their duties under Union law. Other actors shall have access only to the data made available to them in accordance with the provisions set under Union legislation.

10. The Commission shall ensure that the registry:

(a) allows providers of online marketplaces to fulfil the verification obligation referred to in Article 20(1), point (a)(i) and Article 20(1), point (b)(i) by automated technical means and in a way that does not require them to carry out an independent assessment of that content;

(b) provides the data required for online marketplaces to fulfil the verification obligation referred to in Article 20(1), point (a)(ii), if the data required is not included in the public part of the digital product passport, or Article 20(1), point (b)(ii) by automated technical means, including photographs or other pictographic elements that allow the identification of a product, and in a way that does not require them to carry out an independent assessment of that content;

(c) may send notifications referred to in Article 20(2) by automated technical means and in a way that does not require providers of online marketplaces to carry out an independent assessment of that content; and

(d) allows providers of online marketplaces to fulfil the obligation referred to in Article 20(2), point (b) by automated technical means and in a way that does not require them to carry out an independent assessment of that content.

11. The Commission is empowered to adopt delegated acts in accordance with Article 135 to specify any other data which are to be stored in the registry, taking into account:

(a) the need to verify the authenticity and integrity of the digital product passport;

(b) the relevance of the information for improving the efficiency and effectiveness of market surveillance checks and customs controls; and

(c) the need to avoid a disproportionate or excessive administrative burden for economic operators, consumers, and public authorities.

12. The Commission may adopt implementing acts laying down the detailed rules necessary for the implementation and operation of the registry referred to in this Article for the purposes of the digital product passport and product responsibility records, including rules on:

(a) the roles performed in the registry;

(b) access rights and verification procedures for users of the registry;

(c) the structure of the semantic repository, including for the specifications for digital product passports and the product responsibility records;

(d) the data models and technical structures of the digital product passports and the product responsibility records;

(e) the technical procedures for creating, validating and updating the digital product passport;

(f) the technical procedures for creating, validating and updating the product responsibility records, and for electronically registering and confirming mandates relating to those records;

(g) the communication and use of the registrations relevant for the operations of the registry, including the unique registration identifier and of the product responsibility identifier; and

(h) the interconnection of the registry with other information technology systems, including those of public authorities, providers of online marketplaces and digital product passport service providers.

13. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 136(3).

Article 82

Unique registration identifier for products subject to a digital product passport

1. This Chapter shall apply to products for which a digital product passport is required pursuant to this Regulation or other applicable Union law.

2. Where a digital product passport is required for a product pursuant to aligned Union product legislation, the responsible economic operator for products subject to aligned Union product legislation referred to in Article 12 in respect of that product shall obtain a unique registration identifier from the registry before the product is placed on the market or put into service.

3. Where a digital product passport is required for a product pursuant to Union legislation other than aligned Union product legislation, the economic operator designated under that Union legislation shall obtain a unique registration identifier from the registry before the product is placed on the market or put into service.

4. The responsible economic operator referred to in paragraph 2, or the economic operator referred to in paragraph 3, shall register in the registry the unique product identifier of the product concerned as registered pursuant to Article 81, its own unique operator identifier and any other information required by the Union law requiring a digital product passport for that product.

5. Once the registration is completed and validated, the registry shall communicate to the responsible economic operator referred to in paragraph 2, or the economic operator

referred to in paragraph 3, the corresponding unique registration identifier associated with the unique identifiers uploaded for the relevant product model, batch or item. The communication of the unique registration identifier shall not be deemed to be proof of compliance with this Regulation or other Union law.

6. By creating the registration referred to in this Article and using or allowing the use of the unique registration identifier obtained for a product, the responsible economic operator referred to in paragraph 2, or the economic operator referred to in paragraph 3, assumes responsibility for the product pursuant to applicable Union law.

Article 83

Product responsibility identifier for products not subject to a digital product passport

1. This Article shall apply to products subject to Union law for which no digital product passport is required.

2. Where a manufacturer referred to in Article 9(2)(b) designates an authorised representative as the responsible economic operator referred to in Article 9 and before placing a product referred to in paragraph 1 on the market, that manufacturer shall create a product responsibility record, or it may task the authorised representative to do so, by providing in the registry at least the following information:

   (a) the product identifiers which shall include the non-standardised manufacturer product identifier and, if it exists, the standardised manufacturer product identifier, for the product or products covered by the product responsibility record;

   (b) the related model identifiers;

   (c) the commodity codes;

   (d) the unique operator identifier of the manufacturer referred to in Article 9(2)(b);

   (e) the unique operator identifier of the prospective authorised representative;

   (f) photographs or other pictographic elements that allow the identification of the product;

   (g) the period from which the authorised representative will be responsible for the products referred to in Article 9(2); and

   (h) any other information required under Union law.

   The registry shall create a product responsibility identifier and technical and audit-related information necessary for the traceability and verification of the relevant product responsibility records.

3. Both the manufacturer referred to in Article 9(2)(b) and its authorised representative shall confirm the acceptance of the digital mandate in the registry before a product responsibility record may be completed and validated. Either of the parties may invalidate the digital mandate through the registry.

4. Both the manufacturer referred to in Article 9(2)(b) and its authorised representative shall keep the information in the product responsibility record up to date.

5. Once the registration is completed and validated, and for each subsequent amendment of the product responsibility record, the registry shall communicate the relevant

information to the manufacturer referred to in Article 9(2)(b) and its authorised representative.

6. A product responsibility record shall be considered valid only where:

(a) it has been created in accordance with the requirements set out in this Chapter and any other applicable requirements under Union law relating to the creation of the product responsibility record;

(b) it has been duly registered in the registry referred to in Article 81(5); and

(c) it has not been invalidated in the registry by a market surveillance authority, customs authority or other public authorities in accordance with their respective powers under Union law.

TITLE V

MARKET SURVEILLANCE

Chapter 1
MARKET SURVEILLANCE AT MEMBER STATE LEVEL

Article 84

Designation of market surveillance authorities and the single liaison office

1. Member States shall organise and carry out market surveillance as provided for in this Chapter.

2. For the purposes of paragraph 1 of this Article, each Member State shall designate one or more market surveillance authorities in its territory. Each Member State shall inform the Commission and the other Member States of its market surveillance authorities and the areas of competence of each of those authorities alongside a list of legislation for which those authorities are responsible, using the EU Market Surveillance Data Hub referred to in Article 128.

3. Each Member State shall appoint a single liaison office.

4. The single liaison office shall be responsible at least for representing the coordinated position of the market surveillance authorities and the authorities in accordance with Article 121(2) and for communicating the national strategies drawn up in accordance with Article 88. The single liaison office shall also assist in the cooperation between market surveillance authorities in different Member States, provided in Article 100 to Article 104.

5. In order to carry out the market surveillance of products made available online and offline with the same effectiveness for all distribution channels, Member States shall ensure that their market surveillance authorities and single liaison office have the necessary resources, including sufficient budgetary and other resources, such as a sufficient number of competent personnel, expertise, procedures and other arrangements for the proper performance of their duties.

6. Where there is more than one market surveillance authority in their territory, Member States shall ensure that, in respect of each Union harmonisation legislation, the respective duties of those authorities are clearly defined and that appropriate communication and coordination mechanisms are established to enable those authorities to collaborate closely and exercise their duties effectively.

Article 85

Tasks of market surveillance authorities

1. Market surveillance authorities shall conduct their tasks effectively and efficiently in order to ensure the following:

   (a) effective market surveillance within their territory of products made available online and offline with respect to products that are subject to Union harmonisation legislation;

(b) the taking by economic operators of corrective actions; and

(c) the taking of appropriate and proportionate measures where the economic operator fails to take corrective action in order to enforce Union harmonisation legislation.

2. Market surveillance authorities shall exercise their powers and carry out their tasks independently, impartially and without bias.

3. Market surveillance authorities, as part of their tasks set out in paragraph 1 of this Article, shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks based on adequate samples, prioritising their resources and actions to ensure effective and efficient market surveillance and taking into account the national market surveillance strategy drawn up in accordance with Article 88.

In deciding on which checks to perform, on which types of products and on what scale, market surveillance authorities shall follow a risk-based approach taking into account the following factors:

(a) possible hazards and non-compliance concerning a product and, where available, their occurrence on the market;

(b) activities and operations under the control of the economic operator;

(c) the economic operator's past record of non-compliance;

(d) if relevant, the risk profiling performed by the authorities referred to in Article 121(1) and (2);

(e) complaints from end users and other information received from other authorities, economic operators, media and other sources that might indicate non-compliance.

4. The Commission, after consulting the Network, established in accordance with Article 105 of this Regulation and the Consumer Safety Network established in accordance with Article 30 of the Regulation (EU) 2023/988, may adopt implementing acts determining:

(a) the uniform conditions of checks, referred to in paragraph 3 of this Article;

(b) criteria for the determination of the frequency of the checks and the amount of samples to be checked in relation to certain products or categories of products, where specific risks or serious breaches of applicable Union harmonisation legislation have been continuously identified.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with Article 136(3).

5. Where economic operators present test reports or certificates attesting the conformity of their products with aligned Union product legislation issued by a conformity assessment body accredited in accordance with Title III, Chapter 1 of this Regulation, market surveillance authorities shall take due account of those reports or certificates in the exercise of their powers.

6. Evidence that is used by a market surveillance authority in one Member State may be used as part of investigations to verify product compliance carried out by market surveillance authorities in another Member State, without any further formal requirements.

7. Market surveillance authorities shall establish the following procedures in connection with products subject to the Union harmonisation legislation:

   (a) procedures for following up on complaints or reports on issues relating to risks or non-compliance; and

   (b) procedures for verifying that the corrective action that was to be taken by economic operators has been taken.

8. Market surveillance authorities shall make their best effort to cooperate with and utilise findings provided by organisations representing the interests of consumers.

9. With a view to ensuring communication and coordination with their counterparts in other Member States, market surveillance authorities shall actively participate in administrative cooperation groups (ADCOs) as referred to in Article 107.

10. Without prejudice to Article 97, products that have been deemed to be non-compliant on the basis of a decision of a market surveillance authority in one Member State shall be presumed to be non-compliant by market surveillance authorities in other Member States, unless a relevant market surveillance authority in another Member State concluded the contrary on the basis of its own investigation, taking into account the input, if any, provided by an economic operator.

Article 86

Market Surveillance Controls relating to the Digital Product Passport

1. The Commission shall ensure that market surveillance authorities shall have access to relevant data in the digital product passport and the registry for the purpose of carrying their tasks under this chapter.

2. The Commission shall establish and maintain an interconnection between the registry and the EU Market Surveillance Data Hub referred to in Article 128.

3. That interconnection shall enable the verification by the registry, by electronic means, of the market surveillance authorities and of the Union harmonisation legislation for which they are competent. Where a market surveillance authority has been so verified, it shall be authorised to access, retrieve and use non-public data included in the digital product passport and the registry for carrying out their tasks pursuant to Union law based on the access rights rules set in the applicable Union law and national law in compliance with Union law.

4. Market surveillance authorities shall verify the correctness of the digital product passport data regarding the requirements established under the relevant Union law.

5. Such verification shall be recorded in the registry, and the result thereof shall be publicly available through the digital product passport.

Article 87

Peer reviews

1. Voluntary peer reviews shall be organised for market surveillance authorities in order to strengthen consistency in market surveillance activities in relation to the application of this Regulation.

2. The Network established in accordance with Article 105 shall develop the methodology and the rolling plan for peer reviews among participating market

surveillance authorities. When establishing the methodology and the rolling plan, the Network shall take into consideration, at least, the number and the size of market surveillance authorities in the Member States, the number of personnel available and other resources for performing the peer review, and other relevant criteria.

3. Peer reviews shall cover best practices developed by some market surveillance authorities which may be of benefit for other market surveillance authorities, and other relevant aspects related to the effectiveness of market surveillance activities.

4. The outcome of the peer reviews shall be reported to the Network, established in accordance with Article 105.

Article 88

National market surveillance strategies

1. Each Member State shall draw up an overarching national market surveillance strategy, at least every four years. Each Member State shall draw up such strategy no later than one year from the date of entry into force of this Regulation. The Member States shall ensure that the national strategy referred to in the first subparagraph promotes a consistent, comprehensive and integrated approach to market surveillance and to the enforcement of Union harmonisation legislation within their respective territories. When drawing up that strategy, they shall consider all the sectors covered by the Union harmonisation legislation and all stages of the product supply chain, including imports and digital supply chains. They may also consider the priorities set out within the work programme of the Network established in accordance with Article 105.

2. The national market surveillance strategy referred to in paragraph 1 shall include at least the following elements, where that inclusion does not compromise market surveillance activities:

   (a) the available information on the occurrence of non-compliant products, in particular taking into account the checks and controls referred to in Article 85(3) and Article 122, and, where applicable, market trends that may affect non-compliance rates for the categories of products, and possible threats and risks related to emerging technologies;

   (b) the areas the Member States identify as priorities for enforcing the Union harmonisation legislation;

   (c) the enforcement activities planned in order to reduce non-compliance in those areas identified as priorities, including, where relevant, the minimum control levels envisaged for categories of products which have significant levels of non-compliance;

   (d) an assessment of the cooperation with market surveillance authorities in other Member States, as referred to in Article 85(9) and this chapter .

3. Member States shall communicate their national market surveillance strategy to the Commission and other Member States through the EU Market Surveillance Data Hub referred to in Article 128. Each Member State shall publish a summary of its strategy.

Article 89

Information to economic operators

1. The Commission shall ensure, in accordance with Article 2(1) of Regulation (EU) 2018/1724, that the Your Europe portal provides users with easy online access to general information about the product requirements and rights, obligations and rules derived from the Union harmonisation legislation.

2. Member States shall provide economic operators and providers of online marketplaces, at their request and free of charge, with information on the national transposition and implementation of Union harmonisation legislation applicable to products and to the implementation of this Regulation and the Union harmonisation legislation at national level. For this purpose, Article 9(1), (4) and (5) of Regulation (EU) 2019/515 shall apply.

Article 90

Collaborative activities to promote compliance

1. Market surveillance authorities may agree with other relevant authorities or with organisations representing economic operators or end users on the carrying out of collaborative activities that aim of promoting compliance, identify non-compliance, raise awareness and provide guidance in relation to the Union harmonisation legislation with respect to specific categories of products, in particular categories of products that are often found to present a serious risk, including products offered for sale online.

2. The market surveillance authority in question and the parties referred to in paragraph 1 shall ensure that the agreement on collaborative activities does not lead to unfair competition between economic operators and does not affect the objectivity, independence and impartiality of the parties.

3. A market surveillance authority may use any information resulting from collaborative activities for any investigation regarding non-compliance that it undertakes.

4. The market surveillance authority in question shall make the agreement on collaborative activities, including the names of the parties involved, available to the public and shall enter that agreement in the EU Market Surveillance Data Hub referred to in Article 128. The Commission shall make that agreement available on the Safety Gate Portal referred to in Article 25 of Regulation (EU) 2023/988. At the request of a Member State, the Network established in accordance with Article 105 shall assist in the drawing up of the agreement on collaborative activities.

Article 91

Joint actions on market surveillance

1. Market surveillance authorities may agree to conduct joint actions with other market surveillance authorities that aim to promote compliance, identify non-compliance, raise awareness and provide guidance in relation to the Union harmonisation legislation with respect to specific categories of products, including products offered for sale online. A joint action may be carried out across sectors. Market surveillance authorities shall inform the Commission of the abovementioned agreement, its content and the modalities and timing of its execution.

2. Before carrying out a joint action referred to in paragraph 1, participating market surveillance authorities shall agree to adopt a common risk assessment strategy and, unless exceptional circumstances prevent it, to require the relevant economic operators

to take the same corrective or restrictive measures where the same nature of non-compliance has been established.

3. A market surveillance authority may use any information resulting from joint actions for any investigation regarding non-compliance that it undertakes. Where appropriate, the aggregated results may be made available to the public.

Article 92

Powers of market surveillance authorities

1. Member States shall confer on their market surveillance authorities the effective and efficient powers of market surveillance, including investigation and enforcement, necessary for the application of this Regulation and for the application of Union harmonisation legislation.

2. Market surveillance authorities shall exercise the powers provide for in this article efficiently and effectively, to the extent that such exercise relates to the subject matter and the purpose of the measures, the nature and the overall actual or potential harm resulting from non-compliance of products subject to Union harmonisation legislation.

3. When conferring powers in accordance with paragraph 1, Member States may provide for the power to be exercisable in one of the following ways, as appropriate:

   (a) directly by each market surveillance authority under its own authority;

   (b) by recourse to other public authorities in accordance with the division of powers and the institutional and administrative organisation of the Member State in question and in compliance with Union law;

   (c) upon application to courts competent to grant the necessary decision to approve the exercise of that power, including, where appropriate, on appeal, if the application to grant the necessary decision was not successful.

4. The powers conferred on market surveillance authorities in accordance with paragraph 1 shall include at least the following:

   (a) the power to require economic operators to provide relevant documents, technical specifications, data or information on compliance and technical aspects of the product, including access to embedded software in so far as such access is necessary for the purpose of assessing the product's compliance with applicable Union harmonisation legislation, in any form or format and irrespective of the medium of storage or the place where such documents, technical specifications, data or information are stored, and to take or obtain copies thereof;

   (b) the power to require economic operators to provide relevant information on the supply chain, on the details of the distribution network, on quantities of products on the market and on other product models that have the same technical characteristics as the product in question, where relevant for verifying compliance with the applicable requirements laid down in Union harmonisation legislation;

   (c) the power to require economic operators to provide relevant information required for the purpose of ascertaining the ownership of websites, where the information in question is related to the subject matter of the investigation;

   (d) the power to carry out physical checks of products subject to Union harmonisation legislation;

(e) the power to carry out unannounced on-site inspections, including inspections of online and fully digital environments and databases, by entering and inspecting any premises, land or means of transport that the economic operator in question uses for purposes related to the economic operator's trade, business, craft or profession, in order to investigate cases of non-compliance and risk, and the power to obtain evidence both by seizing documents and by asking questions to that economic operator's personnel, which are obliged to reply on the spot;

(f) the power to start investigations on market surveillance authorities' own initiative in order to investigate cases of possible non-compliance or risk for a product subject to Union harmonisation legislation;

(g) the power to take a decision ascertaining the existence of non-compliance or risk for a product subject to Union harmonisation legislation;

(h) the power to require economic operators to take corrective action to bring a case of non-compliance to an end or to eliminate an identified risk;

(i) the power to take appropriate and proportionate measures where the economic operator fails to take corrective action in order to enforce Union harmonisation legislation or where the non-compliance or the identified risk persists, including the power to prohibit or restrict the making available of a product on the market or to order that the product is withdrawn or recalled;

(j) the power, including under a cover identity, to acquire product samples, to inspect them and to reverse-engineer them in order to investigate cases of non-compliance or possible risk;

(k) the power to do either of the following:

i. to issue an order to remove specific content containing or referring to an offer of a non-compliant product and identical content, to disable access to that content, or to require the explicit display of a warning to end users when they access an online interface; such order shall respect the conditions laid down in Article 21(6); or

ii. where a request made in accordance with point (i) has not been complied with, to require information society service providers concerned to restrict access to their relevant online interface, including where necessary by requesting a third party to implement such restriction of access;

(l) the power to refer cases to the respective competent notifying authorities in accordance with Article 23 and national accreditation bodies in accordance with Article 51 in cases where products that have undergone conformity assessment with the same notified body have repeatedly been found to be non-compliant.

(m) the power to impose penalties in accordance with Article 139.

5. Market surveillance authorities may use any information, document, finding, statement, or any intelligence as evidence for the purpose of their investigations, irrespective of the format in which and medium on which they are stored.

Article 93

Interim measures

1. Member States shall confer on their market surveillance authorities the power to take interim measures, including:

   (a) temporary measures prohibiting, suspending or restricting the placing or making available on the market of a product or a specific category or group of products or laying down special conditions for their conformity assessment or for their marketing; or

   (b) the temporary suspension of the economic activities of an economic operator or a provider of online marketplace.

2. The power to take interim measures in accordance with paragraph 1(a) is subject to a determination of the market surveillance authority, on the basis of a preliminary assessment, that a product presents a serious risk.

3. The power to take interim measures in accordance with paragraph 1(b) is subject to a determination of the market surveillance authority, on the basis of a preliminary assessment, that an economic operator or provider of online marketplace has failed to comply with their obligations under this Regulation or in the applicable Union harmonisation legislation, and one of the following conditions is fulfilled:

   (a) over the last eight years, the economic operator has, in at least three cases, failed to comply with the obligations laid down in this Regulation or in the applicable Union harmonisation legislation; or

   (b) over the last eight years, the provider of online marketplaces have, in at least three cases, failed to comply with the obligations laid down in paragraphs 1 and 2 of Article 20.

4. Member States shall inform the Commission and the other market surveillance authorities about such measures through the EU Market Surveillance Data Hub referred to in Article 128.

Article 94

Recovery of costs by market surveillance authorities

1. The Commission and market surveillance authorities may reclaim from the relevant economic operator and, in the circumstances referred to in Article 20(5), from providers of online marketplaces the totality of the costs of their activities with respect to instances of non-compliance or serious risk.

2. The costs referred to in paragraph 1 may include the costs of carrying out testing, the costs of taking measures in accordance with Article 122, the costs of storage and the costs of activities relating to products that are found to be non-compliant or dangerous and are subject to corrective action prior to their release for free circulation or their placing on the market.

Article 95

Market surveillance measures

1. Market surveillance authorities shall take appropriate measures if they make a finding that a product subject to Union harmonisation legislation, when used in accordance with its intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained:

(a) raises a risk; or

(b) does not comply with Union harmonisation legislation.

2. Where market surveillance authorities make findings referred to in paragraph 1, point (a) or paragraph 1, point (b), they shall without delay require the relevant economic operator to take corrective action to bring the non-compliance to an end or to eliminate the risk within a specified period.

3. For the purposes of paragraph 2, the corrective action required to be taken by the economic operator may include:

(a) bringing the product into compliance, including by rectifying formal non-compliance as defined by the applicable Union harmonisation legislation, or by ensuring that the product no longer presents a risk;

(b) preventing the product from being made available on the market;

(c) withdrawing or recalling the product immediately and alerting the public to the risk presented;

(d) destroying the product or otherwise rendering it inoperable;

(e) affixing to the product suitable, clearly worded, easily comprehensible warnings of the risks that it might present, in the language or languages determined by the Member State in which the product is made available on the market;

(f) setting conditions that must be fulfilled in advance for making the product concerned available on the market; and

(g) alerting the end users at risk immediately and in an appropriate and effective form, including by publication of special warnings in the language or languages determined by the Member State where the product is made available on the market.

4. If the economic operator fails to take the corrective measure referred to in paragraph 3 or where the non-compliance or the risk referred to in paragraph 1 persists, market surveillance authorities shall ensure that the product is withdrawn or recalled, or that its being made available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly.

5. When the market surveillance authorities adopt measures in accordance with paragraph 3, point (a) and paragraph 3, point (e), they may also suspend the validity of the digital product passport or the product responsibility record of the product concerned, as applicable, until the product has been brought into compliance. When market surveillance authorities adopt measures in accordance with paragraph 3, point (b), paragraph 3, point (c) and paragraph 3, point (d), the digital product passport or the product responsibility record of the product concerned, as applicable, shall be invalidated.

6. The information required to be submitted to the Commission and the other Member States in accordance with paragraph 4 of this Article shall be communicated through the EU Market Surveillance Data Hub referred to in Article 128. That communication of information shall also be deemed to fulfil notification requirements for the applicable safeguard procedures referred to in Article 98.

7. Where a national measure is considered to be justified in accordance with the applicable safeguard procedure, provided for in Article 98, or where no market

surveillance authority of another Member State concluded the contrary as referred to in Article 98(6), the competent market surveillance authorities in the other Member States shall take the necessary measures in respect of the non-compliant product and shall enter the relevant information in the EU Market Surveillance Data Hub referred to in Article 128.

Article 96

Procedural rights of economic operators

1. Any measure, decision or order taken or issued by market surveillance authorities pursuant to Union harmonisation legislation or this Regulation shall contain an adequate and fact-based statement of reasons.

2. Any measure, decision or order taken or issued in accordance with Article 95(1) shall be communicated without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to it under the law of the Member State concerned and of the time limits to which the exercise of those remedies is subject.

3. Before a measure, decision or order referred to in paragraph 1 is taken or issued, the economic operators concerned shall be given the opportunity to be heard within an appropriate period of no less than 10 working days, unless it is not possible to give the economic operator that opportunity because of the urgency of the measure, in view of health or safety requirements or other grounds relating to the public interests pursued by the relevant Union harmonisation legislation.

   If the measure, decision or order is taken or issued without the economic operator being given the opportunity to be heard, the economic operator shall be given that opportunity as soon as possible thereafter and that measure, decision or order shall, if necessary, be reviewed promptly by the market surveillance authority.

Article 97

Procedure for dealing with products presenting a risk

1. With respect to the aligned Union product legislation, where the market surveillance authorities of one Member State have sufficient reason to believe that a product subject to one or several acts of Union harmonisation legislation presents a risk, they shall carry out an evaluation in relation to the product concerned with regard to all the requirements laid down in this Regulation and the relevant aligned Union product legislation.

2. Where, in the course of the evaluation provided for in paragraph 1, a market surveillance authority finds that a product does not comply with the requirements laid down in any of the relevant and applicable Union legal acts, it shall, without delay, invite the relevant economic operator to take appropriate corrective measures in accordance with Article 95(3) within a reasonable period of time prescribed by the market surveillance authority and taking into account the nature of the risk.

3. When the product concerned has been subject to a conformity assessment involving a notified body, the market surveillance authorities shall inform:

   (a) the notified body concerned;

(b) the relevant notifying authority entrusted with the responsibility to oversee the notified body concerned;

(c) the relevant national accreditation body in cases where the notified body concerned has been accredited.

4. The market surveillance authorities shall inform the Commission and the other Member States of the results of the evaluation and of the corrective actions which they have invited the relevant economic operator to take.

5. The economic operator shall ensure that appropriate corrective action is taken in respect of all the products concerned that the economic operator has made available on the market throughout the Union. The market surveillance authorities shall inform the Commission and the other Member States, without delay, of the corrective action that the economic operator has agreed to take.

6. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 5, the market surveillance authorities shall take any appropriate and proportionate provisional measures referred to in Article 95(3) and shall inform the Commission and the other Member States. These provisional measures shall be applicable only within the jurisdiction of the market surveillance authority having adopted those measures and the assessment supporting these measures shall not be considered binding for any other market surveillance authorities until the expiry of the one month period referred to in paragraph 9.

7. The information referred to in paragraph 6 shall include all available details, in particular the data necessary for the identification of the non-compliant product including the unique product identifier, the origin of that product, 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 authorities shall indicate whether the non-compliance is due to any of the following:

(a) failure of the product to meet the essential or other substantive requirements; or

(b) shortcomings in the harmonised standards, harmonised standardisation deliverables or common specifications referred to in Article 8.

8. Market surveillance authorities of Member States other than the Member State initiating the procedure set out in this Article shall, without undue delay immediately, 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 concerned. If the market surveillance authorities of Member States other than the Member State initiating the procedure set out in this Article disagree with the notified national measure, they shall inform all the Member States and the Commission of their objections referred to in Article 98(2).

9. Where, within one month of receipt of the information referred to in paragraph 6, no objection has been raised by either a market surveillance authority of a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed to be justified for the purposes of the measures referred to in Article 95 and all market surveillance authorities can rely on the technical assessment and conclusions regarding the compliance of the product in question and may proceed with the adoption of their respective decisions referred to in paragraph 11 without the need to conduct a new technical assessment. The Member States other than the Member State initiating the procedure set out in this Article shall ensure that the

appropriate and proportionate restrictive measures referred to in Article 95(3) are taken for their respective jurisdictions without delay in respect of the product concerned and shall inform the Commission and the other Member States of those measures.

10. All information referred to in this Article shall be communicated through the EU Market Surveillance Data Hub referred to in Article 128.

11. This Article shall not apply to non-compliance based on following requirements:

(a) no digital product passport has been registered for the product concerned in accordance with Article 81 and any other requirements set by Union law;

(b) no data carrier has been affixed on the product in accordance with Article 67;

(c) the technical documentation is either not available or not complete;

(d) the information referred to in Article 12(7) is absent, false or incomplete.

Article 98

Union safeguard procedure

1. On completion of the procedure provided for in Article 97(5) and Article 97(6), a Member State or the Commission may raise objections against a measure taken by another Member State if it has reasons to believe that a national measure may be contrary to Union law.

2. Objections raised by a Member State in accordance with paragraph 1 shall be duly justified and substantiated by pertinent factual evidence and legal arguments. They shall contain at least the following elements:

(a) a description of the nature of the risk or non-compliance identified;

(b) the reasons why the results of the notified measure are being contested;

(c) the results of tests or assessments carried out on the product concerned by the objecting Member State or on its behalf.

3. When an objection is raised pursuant to paragraph 1, the Commission shall, without undue delay, enter into consultation with the Member States and the economic operators concerned and shall evaluate that national measure on the basis of the elements presented by stakeholders.

4. On the basis of the results of that evaluation provided for in paragraph 1, the Commission shall decide by adopting an implementing act in accordance with the examination procedure referred to in Article 136(3) determining whether the national measure is justified or not, with regards to the provisions of this Regulation, the aligned Union product legislation, the Charter of fundamental rights and the general principles of Union law, and where necessary, propose appropriate corrective measures.

5. The Commission shall address its decision to all Member States and shall, without delay, communicate it to them and the economic operators concerned.

6. If in its decision referred to in paragraph 4 the Commission finds that the national measure is considered to be justified with regards to the provisions of this Regulation, the aligned Union product legislation, the Charter of fundamental rights and the general principles of Union law, the market surveillance authorities of each Member States shall take the measures necessary to ensure that the non-compliant product is withdrawn from market in that Member State or recalled therefrom, and shall inform

the Commission accordingly. Where the non-compliance of the product is attributed to shortcomings in the harmonised standards, harmonised standardisation deliverables or common specification referred to in Article 8 the Commission shall apply the procedure provided for in Article 33 of the Regulation (EU) XXXX/XXXX [new Standardisation Regulation on formal objection procedure].

7. If in its decision referred to in paragraph 4 the Commission finds that the national measure referred to in paragraph 1 is not justified with regards to this Regulation, the applicable aligned Union product legislation, the Charter of fundamental rights or the general principles of Union law, the Member State that is the addressee of the decision shall withdraw it.

Article 99

Compliant products which present a risk to health and safety

1. Where, while carrying out an evaluation in accordance with Article 97, a Member State finds that although a product complies with all of the relevant and applicable Union legal acts, it presents a risk, it shall require the economic operator concerned to take corrective action in respect of all the items of that product that it has made available on the market throughout the Union.

2. The Member State referred to in paragraph 1 shall immediately inform the Commission and the other Member States of the results of the evaluation and of the corrective actions which that Member State has required the relevant economic operator to take via the EU Market Surveillance Data Hub referred to in Article 128**.** That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

3. The Commission shall without undue delay enter into consultation with the Member States and the economic operators concerned and shall evaluate the national measures referred to in paragraph 2 on the basis of the elements presented by all the relevant stakeholders.

4. On the basis of the results of the evaluation referred to in paragraph 2 the Commission shall by adopting an implementing act in accordance with the urgency procedure referred to in Article 136(3) decide whether the national measures are justified with regards to this Regulation, the applicable aligned Union product legislation, the Charter of fundamental rights or the general principles of Union law and where necessary, propose appropriate corrective measures.

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the economic operators concerned.

Article 100

Mutual assistance

1. The market surveillance authorities shall provide mutual assistance to one another as well as to the Commission and to the relevant Union agencies. They shall cooperate effectively and efficiently with one another as well as with the Commission and with the relevant Union agencies.

2. For the purpose of paragraph 1, mutual assistance shall in particular take the form of:

(a) requests for information in accordance with Article 101;

(b) requests for expertise in accordance with Article 102; and

(c) requests for enforcement measures in accordance with Article 103.

Article 101

Request for information

1. If a market surveillance authority is unable to conclude an investigation as referred to in Article 92(4), point (f) because of its inability to access certain information, despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the market surveillance authority of another Member State where access to this information can be enforced.

2. The requested authority referred to in paragraph 1 shall undertake appropriate investigations or take any other measures that are appropriate in order to gather the requested information. Where necessary, those investigations shall be carried out with the assistance of other market surveillance authorities. It shall also supply to the applicant authority without delay, and in any event within a period of 30 days from the date of the request, any information that the requested authority considers to be relevant for the investigation of the requesting authority.

3. The applicant authority referred to in paragraph 1 shall remain responsible for the investigation that it has initiated, unless the requested authority agrees with the applicant authority to take over responsibility for that investigation.

4. In duly justified cases, a requested authority may refuse to comply with a request for information referred to in paragraph 2 where:

(a) the applicant authority has not sufficiently substantiated why the requested information is necessary and proportionate in order to establish non-compliance;

(b) the requested authority puts forward convincing grounds demonstrating that complying with the request referred to in paragraph 1 would substantially impair the execution of its own tasks.

Article 102

Request for expertise

1. When a market surveillance authority is unable to conclude an investigation because it requires technical support or expert knowledge on the requirements of relevant Union harmonisation legislation and on the characteristics of the products at issue, despite having made all appropriate efforts to obtain such support and knowledge, it may submit a reasoned request to the market surveillance authority of another Member State to make them available to it. To that end, the requested authority shall make best efforts to provide to the applicant authority, without undue delay, and at the latest within a period of 30 days from the date of the request, any support and knowledge that it considers to be relevant in order to establish whether a product is non-compliant.

2. The applicant authority shall remain responsible for any investigation that it has initiated, unless the requested authority agrees with the applicant authority to take over responsibility.

3. In duly justified cases, a requested authority may refuse to comply with a request for expertise or support referred to in paragraph 1 where:

(a) the applicant authority has not sufficiently substantiated why their requested aide is necessary and proportionate in order to establish non-compliance;

(b) the requested authority puts forward convincing grounds demonstrating that complying with the request would substantially impair the execution of its own tasks.

Article 103

Request for enforcement measures

1. Where bringing non-compliance with regard to a product to an end requires measures within the jurisdiction of another Member State and where such measures do not result from the requirements of Article 95(7), an applicant authority may submit a duly reasoned request for enforcement measures to an authority in that other Member State (the requested authority).

2. The requested authority referred to in paragraph 1 shall, without delay, take all appropriate and necessary enforcement measures in order to bring the non-compliance referred to in paragraph 1 to an end by exercising the powers laid down in Article 92 and any additional powers granted to it under national law in conformity with Union law.

3. The requested authority referred to in paragraph 1 shall inform the applicant authority about the enforcement measures referred to in paragraph 2 that it has taken or which it intends to take.

A requested authority may refuse to comply with a request for enforcement measures in any of the following situations:

(a) the requested authority concludes that the applicant authority has not provided sufficient information in order to establish non-compliance;

(b) the requested authority considers that the request is contrary to Union harmonisation legislation;

(c) the requested authority puts forward convincing grounds demonstrating that complying with the request would substantially impair the execution of its duties or the exercise of its powers.

Article 104

Procedure for mutual assistance requests

1. Before submitting a request in accordance with Article 101, Article 102 or Article 103, the applicant authority shall endeavour to carry out all reasonable possible investigative measures.

2. When submitting a request in accordance with Article 101, Article 102 or Article 103, the applicant authority shall provide all available information in order to enable the requested authority to fulfil the request, including any necessary evidence obtainable only in the Member State of the applicant authority.

3. Requests made in accordance with Article 101, Article 102 or Article 103 and all communication related to them shall be submitted using electronic standard forms by means of the EU Market Surveillance Data Hub referred to in Article 128.

4. All communication related to requests made in accordance with Article 101, Article 102 and Article 103 shall take place directly between the involved market surveillance authorities or through the single liaison offices of the Member States concerned.

5. The languages to be used for requests made in accordance with Article 101, Article 102 and Article 103 and for all communication related to them shall be agreed upon by the market surveillance authorities concerned.

6. Where no agreement about the languages to be used can be reached between the market surveillance authorities concerned, the requests made in accordance with Article 101, Article 102 and Article 103 shall be sent in the official language of the Member State of the applicant authority, and the replies to such requests shall be sent in the official language of the Member State of the requested authority. In such case, the applicant authority and the requested authority shall arrange for the translation of the requests, replies or other documents that they receive from the other authority.

7. The EU Market Surveillance Data Hub referred to in Article 128 shall provide structured information on mutual assistance cases to the single liaison offices involved. Using this information, single liaison offices shall provide any support that is necessary to facilitate assistance.

Chapter 2
COORDINATION AND COOPERATION IN MARKET SURVEILLANCE

Article 105

Union Product Compliance Network

1. A Union Product Compliance Network (‘the Network’) is hereby established.

2. The purpose of the Network is to serve as a platform for structured, effective and efficient coordination and cooperation between enforcement authorities of the Member States with each other and the Commission, and to streamline, strengthen and facilitate the practices of market surveillance within the Union, thereby making market surveillance more effective and efficient.

3. The Network shall be composed of:

   (a) one representative of each single liaison office referred to in Article 84 and optionally one national expert from each Member State;

   (b) the chairs of ADCOs established in accordance with Article 107, first paragraph; and

   (c) representatives from the Commission.

4. The Network shall meet at regular intervals and, where necessary, at the reasoned request of the Commission or a Member State.

5. The Network may establish standing or temporary sub-groups dealing with specific questions and tasks.

6. The Network shall invite a representative of the Consumer Safety Network referred to in Article 30 of Regulation (EU) 2023/988 to participate in relevant meetings and activities of the Network, so that that representative may contribute to its activities in relation to product safety and coordination of market surveillance of Union product legislation.

7. The Network may invite experts and other third parties, including the organisations representing the interests of industry, SMEs, consumers, testing laboratories, standardisation and conformity assessment bodies at Union level, to attend meetings as observers or to provide written contributions.

8. The Network shall use its best endeavours to reach consensus. Decisions taken by the Network shall be recommendations, thus legally non-binding.

9. The Network shall establish its own rules of procedure.

Article 106

Role and task of the Network

1. The Network established in accordance with Article 105(1) shall have the following tasks:

   (a) to prepare, adopt and monitor the implementation of its work programme;

   (b) to facilitate the identification of common priorities for market surveillance activities and the exchange of information across sectors on evaluations of products, including risk assessment, test methods and results, recent scientific developments and new technologies, emerging risks and other aspects relevant to control activities and on the implementation of national market surveillance strategies and activities;

   (c) to coordinate ADCOs established in accordance with Article 107, first paragraph and their activities;

   (d) to organise a minimum of 38 joint actions per year, or as many joint actions as the number of ADCOs, to be carried out in accordance with Article 91 and define their priorities;

   (e) to exchange expertise and best practices, in particular regarding the implementation of national market surveillance strategies;

   (f) to facilitate the organisation of training programmes, exchanges of personnel, and peer reviews referred to in Article 87;

   (g) in collaboration with the Commission, to organise information campaigns and voluntary mutual visit programmes between market surveillance authorities;

   (h) to discuss questions arising from the practice of mutual assistance mechanisms;

   (i) to contribute to the development of guidance to ensure the effective, efficient and uniform application of this Regulation;

   (j) to propose the financing of the activities referred to in Article 129;

   (k) to contribute to uniform administrative practices with regard to market surveillance in the Member States;

(l) to provide advice and assist the Commission with issues related to the further development of the EU market surveillance data hub referred to in Article 128 and Safety Gate Alert System referred to in Article 123;

(m) to promote the cooperation and exchange of expertise and best practices between market surveillance authorities and authorities in charge of controls at the Union's external borders;

(n) to promote and facilitate collaboration with other relevant networks and groups, with a view to explore possibilities for using new technologies for the purposes of market surveillance, including the traceability of products;

(o) to evaluate regularly the national market surveillance strategies, drawn up in accordance with Article 88;

(p) to take up any other issues in activities within the remit of the Network, established in accordance with Article 105, with the aim of contributing to the effective functioning of market surveillance within the Union.

2. When considering joint actions referred to in paragraph 1, point (d), the Commission and the Member States shall undertake their best effort to organise and conduct such project in an efficient and effective manner.

3. In carrying out the tasks set out in paragraph 1, the Network established in accordance with Article 105(1) shall address general and horizontal issues of market surveillance with a view to facilitating the cooperation among single liaison offices, as well as the Commission.

Article 107

Administrative Cooperation groups

1. Separate or joint Administrative Cooperation groups (ADCOs) shall be established, within the institutional framework of the Network established in accordance with Article 105, to facilitate the uniform application of Union harmonisation legislation. To that end, ADCOs shall in particular:

(a) ensure structured administrative cooperation of market surveillance authorities; and

(b) carry out coordinated market surveillance on products that may present a risk in at least two Member States.

2. In order to ensure structured administrative cooperation of market surveillance authorities referred to in paragraph (1)(a), ADCOs shall be composed of representatives of the national market surveillance authorities and, if appropriate, representatives of the single liaison offices.

3. In order to carry out coordinated market surveillance referred to in paragraph (1)(b), ADCOs shall be composed of seconded national experts that are employed and put at disposal of ADCOs by the Member States. Each Member States shall put at the disposal of ADCOs at least one expert per separate or joint ADCO. Such expert may be the representatives of the national market surveillance authorities referred to in paragraph 1.

4. ADCO meetings shall be intended only for representatives of market surveillance authorities and the Commission. With respect to ADCO meetings that ensure structured administrative cooperation of market surveillance authorities referred to in

paragraph 1, point (a), Union agencies and relevant stakeholders, such as organisations representing the interests of industry, small and medium-sized enterprises (SMEs), consumers, testing laboratories, standardisation and conformity assessment bodies at Union level, may be invited to attend.

5. In order to ensure structured administrative cooperation of market surveillance authorities pursuant to paragraph 1, point (a), ADCOs shall meet at regular intervals and, where necessary, at the reasoned request of the Commission or a Member State.

6. In order to carry out coordinated market surveillance pursuant to paragraph 1, point (b), ADCOs shall meet each two weeks or whenever necessary.

7. ADCOs shall establish their own rules of procedure.

8. ADCOs shall use their best endeavours to reach consensus. Decisions taken by the ADCOs shall be recommendations, thus legally non-binding.

Article 108

Role and task of the ADCOs

1. In order to pursue the objective referred to in Article 107, paragraph 1, point (a), ADCOs shall carry out the following tasks:

   (a) promote communication between market surveillance authorities and the Network established in accordance with Article 105(1) and develop mutual confidence between market surveillance authorities;

   (b) develop common practices and methodologies for effective market surveillance;

   (c) inform each other of national market surveillance methods and activities and to develop and promote best practices;

   (d) identify issues of shared interest relating to market surveillance and suggest common approaches to be adopted; and

   (e) facilitate sector-specific evaluations of products, including risk assessments, test methods and results, recent scientific developments and other aspects relevant to control activities.

2. In order to pursue the objective referred to in Article 107, paragraph 1, point (b), ADCOs shall carry out the following tasks:

   (a) assess any information, including information brought to attention of the group by one or more of its experts or received from economic operators, media and other sources, that might indicate non-compliance;

   (b) decide whether to open coordinated market surveillance aimed at determining whether applicable Union harmonisation legislation has been infringed, following a risk-based approach referred to in Article 85(3);

   (c) decide whether coordinated market surveillance may be carried out either:

      (a) by the market surveillance authority of one expert acting on behalf of ADCO; or

      (b) by multiple market surveillance authorities of the experts of ADCOs in a coordinated way;

(d) if coordinated market surveillance carried out pursuant by point (c) leads to a finding that the product at issue does not conform to applicable Union harmonisation legislation, recommend that relevant national market surveillance authorities of the Member States:

i. require economic operators on their territories to take appropriate corrective action to bring a case of non-compliance to an end or to eliminate the risk; and

ii. take appropriate measures where an economic operator fails to take appropriate corrective action or where the non-compliance or the risk persists, including the power to prohibit or restrict the making available of a product on the market or to order that the product is withdrawn or recalled.

3. The market surveillance authority of the expert carrying out coordinated market surveillance on behalf of the ADCO provided for in Article 107, paragraph 1, point (b) shall:

(a) exercise the powers laid down in Article 107 and any additional powers granted to it under national law;

(b) act in accordance with Article 91;

(c) keep the ADCO informed about the development of the investigation.

The Commission may use the powers of coordination in accordance with Article 118, if so requested by the ADCO.

Article 109

Tasks of the Commission within the Network

The Commission shall carry out the following tasks within the Network:

(a) to support and encourage cooperation between market surveillance authorities through the Network established in accordance with Article 105(1) and participate in the meetings of the Network, its sub-groups and the ADCOs;

(b) to assist the Network, its sub-groups, and the ADCOs by means of an executive secretariat that provides technical and logistic support;

(c) to keep and make available to the single liaison offices and ADCO chairs an updated list of ADCO chairs, including their contact information;

(d) to assist the Network in preparing and monitoring its work programme, and in preparation of peer reviews referred to in Article 87;

(e) to support the functioning of the Product Contact Points established under Regulation (EU) 2019/515;

(f) to determine, in consultation with the Network, the need for additional testing capacity and to propose solutions for that purpose, in accordance with Article 111;

(g) to provide support for the establishment of separate or joint ADCOs established in accordance with Article 107;

(h) to assist ADCOs in carrying out their enforcement tasks referred to in Article 108;

(i) to assist the Network to perform preliminary or ancillary work in connection with the implementation of market surveillance activities related to the application of Union harmonisation legislation, such as studies, programmes, evaluations, comparative analyses, mutual joint visits and visit programmes, exchange of personnel, research work, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work;

(j) to organise joint actions in accordance with Article 91 and common training programmes, to facilitate exchanges of personnel between market surveillance authorities and, where appropriate, with the market surveillance authorities of third countries or with international organisations, and to organise information campaigns and voluntary mutual visit programmes between market surveillance authorities;

(k) to examine, at the request of the Network or on its own initiative, any question covering the application of this Regulation and issue guidelines, recommendations and best practices in order to encourage the consistent application of this Regulation.

Article 110

International cooperation

1. In order to improve the efficiency of market surveillance in the Union, the Commission may cooperate with and exchange market surveillance related information with regulatory authorities of third countries or international organisations within the framework of agreements concluded between the Union and third countries or international organisations. Any such agreements shall be based on reciprocity, include provisions on confidentiality corresponding to those applicable in the Union, and ensure that any exchange of information is in accordance with applicable Union law and in compliance with human rights.

2. The cooperation or exchange of information may relate, inter alia, to the following:

   (a) risk assessment methods used and the results of product-testing;

   (b) coordinated product recalls or other similar actions;

   (c) measures taken by market surveillance authorities in accordance with Article 95.

3. The Commission may approve a specific system of product-related pre-export control carried out by a third country on products immediately prior to their export to the Union in order to verify that those products satisfy the requirements of the Union harmonisation legislation applicable to them. The approval may be granted in respect of one or more products, in respect of one or more categories of products or in respect of products or categories of products manufactured by certain manufacturers.

4. The Commission shall produce and maintain a list of those products or categories of products with regard to which approval has been granted in accordance with paragraph 3 and shall make this list available to the public.

5. Approval may only be granted to a third country in accordance with paragraph 3 if the following conditions are satisfied:

   (a) the third country possesses an efficient verification system of the compliance of products exported to the Union, and the controls carried out in that third country are sufficiently effective and efficient to replace or reduce import controls;

(b) audits within the Union and, if relevant, in the third country demonstrate that products exported from that third country to the Union satisfy the requirements set out in Union harmonisation legislation.

6. Where an approval has been granted in accordance with paragraph 3, the risk assessment applied to import controls for those products or categories of products entering the Union market, referred to in that paragraph, shall include the granted approvals.

The authorities referred to in Article 121(1) and (2) may, however, carry out controls on those products entering the Union market, including in order to ensure that the pre-export controls carried out by the third country are effective to determine compliance with Union harmonisation legislation.

7. The approval referred to in paragraph 3 shall specify the competent authority of the third country under whose responsibility the pre-export controls are to be performed and that competent authority shall be the counterpart for all contacts with the Union.

8. The competent authority, referred to in paragraph 7, shall ensure the official verification of the products prior to their entry into the Union.

9. Where the controls on products entering the Union market referred to in paragraph 3 of this Article reveal significant non-compliance, the market surveillance authorities shall notify immediately the Commission through the EU market surveillance data hub referred to in Article 128 and adapt the level of controls on such products.

10. The Commission shall adopt implementing acts approving each specific system of product-related pre-export controls, referred to in paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 136(3).

11. The Commission shall regularly monitor the correct functioning of the approval granted under paragraph 3 of this Article. The Commission shall adopt implementing acts withdrawing that approval where it is revealed that the products entering the Union market do not comply with Union harmonisation legislation in a significant number of cases. Those implementing acts shall be adopted in accordance with Article 136(3). The Commission shall immediately inform the third country concerned thereof.

12. The system of product-related pre-export control shall be evaluated in accordance with Article 151(3).

Article 111

Union testing facilities

1. Union testing facilities shall contribute to enhancing laboratory capacity, as well as to ensuring the reliability and consistency of testing, for the purposes of market surveillance within the Union.

2. For the purposes of paragraph 1, the Commission may designate a public testing facility of a Member State or an entity owned by a professional or a cooperative association based in a Member State as a Union testing facility for specific categories of products or for specific risks related to a category of products.

3. The Commission may also designate one of its own testing facilities as a Union testing facility for specific categories of products or for specific risks related to a category of products, or for products for which testing capacity is missing or is not sufficient.

4. The Union testing facilities shall be accredited in accordance with Title III, Chapter 5.

5. The designation of Union testing facilities shall not affect the freedom of market surveillance authorities, the Network established in accordance with Article 105(1) and the Commission to choose testing facilities for the purpose of their activities. The Union testing facilities may provide their services to market surveillance authorities, the Network, the Commission, other government or intergovernmental entities and private operators. The Union testing facilities must react expediently to the requests for testing.

6. The Union testing facilities cannot be at any time in a situation of professional conflicting interests regarding the products they deal with.

7. The Union testing facilities shall, within the area of their competence, perform the following activities:

   (a) carry out the testing of products at the request of market surveillance authorities, the Network or the Commission;

   (b) provide independent technical or scientific advice at the request of the Network;

   (c) where applicable, develop new techniques and methods of analysis;

   (d) conduct, at the request of the Network, established in accordance with Article 105(1), training courses for the benefit of staff of market surveillance authorities and the Commission;

   (e) organise workshops, at the request of the Network, established in accordance with Article 105(1), to present their activities;

   (f) where applicable, participate at the meetings of the coordination groups of the Notified Bodies for specific categories of products where they are designated;

   (g) where applicable, participate in the work of standard development organisations at Union level.

8. The activities referred to in paragraph 7 of this Article shall be remunerated and may be financed by the Union in accordance with Article 129(2). The fees charged by the Union testing facilities must be reasonable and proportionate to the services rendered.

9. Union testing facilities may receive financing by the Union in accordance with Article 129(2) in order to increase their testing capacity or to create new testing capacity for specific categories of products or for specific risks related to a category of products.

10. The Commission shall adopt implementing acts specifying the procedures for the designation of the Union testing facilities. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 136(3).

Article 112

Digital product passport national coordinators

1. Each Member State shall appoint a national coordinator. The national coordinator shall:

   (a) act as a contact point for their respective administrations for all matters relating to the digital product passport;

   (b) manage registry access rights for the competent national authorities for their respective Member State.

2. Each Member State may, in accordance with its internal administrative structure, appoint one or more coordinators in order to carry out any of the tasks listed in paragraph 1. One national coordinator for each Member State shall be responsible for contacts with the Commission in respect of all matters relating to the digital product passport.

3. At the latest by **.....** each Member State shall inform the other Member States and the Commission of the name and contact details of its national coordinator.

Article 113

Digital Product Passport Coordination Group

A coordination group is hereby established ('the Digital Product Passport Coordination Group'). It shall be composed of one national coordinator from each Member State and shall be chaired by a representative of the Commission. It shall adopt its rules of procedure and shall closely collaborate with other expert groups including those related to market surveillance and customs. The Commission shall provide the secretariat.

Article 114

Role and tasks of the Digital Product Passport Coordination Group

The Digital Product Passport Coordination Group shall support the implementation of Title IV, Chapter 1 of this Regulation. In particular it shall:

(a) facilitate the exchange and regular updating of best practices;

(b) discuss needs for improvements to the registry and the digital product passport web portal;

(c) discuss matters relating to digital product passport interoperability;

(d) advise the Commission in the preparation of guidance documents for users of the registry;

(e) advise the Commission in carrying out evaluations of the Commission Implementing Regulation on the registry.

Chapter 3

MARKET SURVEILLANCE AT UNION LEVEL

Article 115

Powers of monitoring and evaluation

1. The Commission shall monitor and evaluate the application by the Member States of Title V Chapter 1, Chapter 4, and Chapter 5, in particular the application of the obligation to ensure that the market surveillance authorities in their respective territories:

(a) have the necessary powers and resources for the proper performance of their tasks;

(b) perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks based on adequate samples.

2. The Commission shall monitor and evaluate the application by Member States of Chapters 1, 4, and 5 of Title V, including by conducting visits pursuant to paragraph 3 to paragraph 7.

3. The Commission shall prioritise its monitoring and evaluation on Members States based on the indicators referred to in paragraph 9.

4. The Commission visits may cover market surveillance authorities and authorities designated in accordance with Article 121(2). The Commission shall conduct such visits in a transparent, effective, harmonised and consistent manner. The Commission shall give at least two months' notice of a visit to the appropriate authority in whose territory it is to be conducted. The staff of the Commission that conduct the visit shall be accompanied by a representative of the relevant authority when carrying out the on-the-spot visits. The conducting of the visits shall be based on a systematic gathering of information, including through interviews and examination of documents.

5. Member States shall effectively cooperate with the Commission in the accomplishment of its visit tasks during the preparatory, monitoring and reporting phases. In particular, Member State shall ensure that, upon request, the staff of the Commission that conduct the visit have access to any relevant documentation and shall, by any means within their legal powers, assist the Commission to accomplish its task in full if the staff of the Commission that conduct the visit encounter difficulties in the execution of their duties.

6. Within six weeks from the date of completion of a visit, the Commission shall communicate to the Member State a visit report. The report shall set out the findings of the staff of the Commission that conduct the visit and may contain recommendations for action.

7. Within three months from the date of dispatch of a visit report, the Member State shall submit in writing to the Commission an answer to the report which addresses the findings and recommendations and provides an action plan, specifying actions and deadlines, to remedy any identified deficiencies. Where the visit report identifies no deficiencies, no answer shall be required.

8. Following receipt of the answer from the Member States, the Commission may conduct a follow-up visit. An appropriate authority shall be given at least two weeks' notice of a follow-up visit to be conducted on its territory. The main focus of follow-up visit shall be the areas where deficiencies were identified during the initial Commission inspection.

9. Member States shall communicate to the Commission, no later than two years from the date of the adoption of the implementing act referred to in paragraph 10 and every year thereafter, data concerning the application of Title V Chapter 1, Chapter 4, and Chapter 5.

10. The Commission shall, by means of implementing acts, determine the output indicators on the basis of which Member States are to communicate the data referred to in paragraph 9 of this Article. Such indicators shall include the failure to open an investigation following a Commission notification sent in accordance with Article 117. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 136(3).

Article 116

Powers of direct investigation and enforcement

1. The Commission, either at its own initiative or at the request of a Member State or of consumer or business organisations, is empowered to carry out investigations and enforcement actions with respect to products entering the Union market that originate in third countries, if the conditions laid down in paragraph 2 are met and in accordance with paragraph 3 to paragraph 6.

2. The Commission may exercise powers referred to in paragraph 1 if it determines that the following conditions are met:

   (a) non-compliant products that present a risk may be placed or are likely to be placed on the Union market in at least two-thirds of the Member States; and

   (b) Member States have opened no market surveillance investigation to enforce Union harmonisation legislation, after receiving a Commission notification sent in accordance with Article 117.

3. For the purposes of paragraph 1, the Commission is empowered to acquire product samples, including under a cover identity, and to organise and carry out, at its own expense, tests and inspections of those samples. The Commission may entrust the performance of such tests and inspections to testing laboratories, in which case the testing laboratories shall be acting on behalf of the Commission.

4. If the Commission determines that the product at issue does not fulfil the requirements laid out in the applicable Union harmonisation legislation, it is empowered to:

   (a) require the economic operators concerned to take corrective action to bring an instance of non-compliance to an end or to eliminate the risk; or

   (b) where an economic operator fails to take corrective action or where the non-compliance or the risk persists, prohibit or restrict the making available of the product on the market or to order that that product is withdrawn or recalled;

   (c) do either of the following:

      i. to issue an order to remove specific content containing or referring to an offer of a non-compliant product and identical content, to disable access to that content, or to require the explicit display of a warning to end users when they access an online interface; such order shall respect the conditions laid out in Article 21(5); or

      ii. where a request made in accordance with point (i) has not been complied with, to require information society service providers concerned to restrict access to their relevant online interface, including where necessary by requesting a third party to implement such restriction of access;

   (d) impose penalties on the economic operators that have failed to take the required corrective action pursuant to Article 140;

   (e) suspend the validity of the digital product passport or the product responsibility record of the product concerned, as applicable, until the product has been brought into compliance;

   (f) take interim measures including:

      i. temporary measures prohibiting, suspending or restricting the placing or making available on the market of a product or a specific category or group

of products, or laying down special conditions for their conformity assessment or for their marketing; or;

ii. the temporary suspension of the economic activities of an economic operator or a provider of online marketplace.

To that end, the Commission shall take implementing acts in accordance with Article 136(3). By derogation to the preceding sentence, on duly justified imperative grounds of urgency relating to the health and safety of consumers and other end-users, the Commission may adopt immediately applicable implementing acts in accordance with Article 136(4).

5. The power to take interim measures:

(a) in accordance with paragraph 4(f)(i) is subject to a determination of the Commisssion, on the basis of a preliminary assessment, that a product presents a serious risk.

(b) in accordance with paragraph 4(f)(ii) is subject to a determination of the Commission, on the basis of a preliminary assessment, that an economic operator or provider of online marketplace has failed to comply with their obligations under this Regulation or in the applicable Union harmonisation legislation, and one of the following conditions is fulfilled:

i. over the last eight years, the economic operator has, in at least three cases, failed to comply with the obligations laid down in this Regulation or in the applicable Union harmonisation legislation; or

ii. over the last eight years, the provider of online marketplaces have, in at least three cases, failed to comply with the obligations laid down in paragraphs 1 and 2 of Article 20.

6. If the Commission adopts an implementing act pursuant to paragraph 4, point (e), the digital product passport or the product responsibility record of the product concerned, as applicable, shall be invalidated.

7. The Commission shall exercise powers of investigation and enforcement referred to in paragraph 1 in accordance with Article 96.

8. This Article shall apply without prejudice to the Union enforcement powers exercised in accordance with:

(a) Article 75 of Regulation (EU) 2024/1689;

(b) Article 56 (3) to (6) of Regulation (EU) 2024/2847.

Article 117

Commission notifications to Member States in the context of direct investigation and enforcement

1. The Commission may notify Member States that it has become aware that a product presenting a risk may be found on their territories and request those Member States to initiate the market surveillance activities in accordance with Article 100 or explain their refusal to initiate such activities where all of the following conditions occur:

(a) no market surveillance activities have been initiated by any Member State in relation to the product concerned; and

(b) the product may be placed on the market or is likely to be placed on the market under the conditions referred to in Article 116(2), point (a) .

2. The Commission shall make the notification referred to in paragraph 1 through the EU Market Surveillance Data Hub referred to in Article 128. The Member States notified in accordance with paragraph 1 shall respond within two weeks following from the date of receipt of the notification or a shorter period in cases of absolute urgency for health and safety reasons, by informing the Commission and the other Member States of the market surveillance actions that they have initiated or alternatively, by providing a justification for their refusal to take such actions.

3. Where the Member State fails to respond within the time limit provided for in paragraph 2, or opened no market surveillance investigation, the Commission may adopt the measures referred to in o Article 116(4).

Article 118

Powers of coordination

1. Where market surveillance authorities conduct joint actions with other market surveillance authorities in accordance with Article 91, the Commission shall assist them including by:

(a) selecting the product sectors on which such joint actions shall be carried out;

(b) managing the operational coordination of the joint actions; and

(c) managing the financial coordination of the joint actions.

2. When market surveillance authorities conduct collaborative activities in accordance with Article 90 or carry out coordinated market surveillance on behalf of the ADCO in accordance with Article 108(2), point (c), the Commission may assist them in accordance with paragraph 1, at its own initiative or when requested by the relevant authorities or by the ADCO.

3. The Commission shall apply the instruments of international cooperation referred to in Article 110.

Article 119

Union market surveillance fee

1. Customs authorities shall collect a Union market surveillance fee of a fixed amount per item within the meaning of Article 5(78) of Regulation XXXX/XXXX (nUCC) to cover the estimated costs of the services to be rendered for carrying out market surveillance on products entering the Union market within the meaning of Article 4, point (70).

2. The amount of the Union market surveillance fee referred to in paragraph 1 shall correspond to the approximate costs of the services referred to in that paragraph. Those costs shall include at least:

(a) the costs incurred by the market surveillance authorities for the activities necessary to exercise the powers of market surveillance, investigation and enforcement under Article 92; and

(b) the costs incurred by the Union for the activities necessary to exercise the powers of evaluation and monitoring under Article 115, the powers of direct

investigation and enforcement under Article 116 and the powers of coordination under Article 118.

3. The amount referred to in paragraph 2 shall be lower where the subject of the release for free circulation is imported goods that are:

(a) not sold in distance sales, or

(b) sold in distance sales but from a customs warehouse for distance sales as referred to in Article 145 of Regulation XXXX/XXXX [nUCC, customs warehouses for distance sales].

4. The Commission shall draw periodic reports to assess the need to adjust the approximate costs of services and activities indicated in paragraph 1 and paragraph 2. Such reports shall be taken into account for determining the amount of the Union market surveillance fee chargeable each year in accordance with paragraph 2.

5. The debtor of the customs debt at import shall pay the Union market surveillance fee at least once a month to the customs authorities competent for the release for free circulation of the goods at the moment of the payment of the customs debt. Where there is no customs debt, the person that would have been the debtor in case of a customs debt shall be the debtor. In matters not regulated, the provisions on customs debt referred to in Regulation XXXX/XXXX [revised UCC] shall apply mutatis mutandis to the Union market surveillance fee.

6. The Union market surveillance fee shall be non-refundable.

7. The Commission is empowered to adopt delegated acts to supplement this Article:

(a) by further specifying the criteria for establishing the amount of the Union market surveillance fee in accordance with paragraphs 2 and 3;

(b) by setting out the procedure, practical arrangements and modalities for applying and collecting the Union market surveillance fee per item from the economic operator.

8. These delegated acts shall be adopted in accordance with Article 135.

9. The amount of the Union market surveillance fee to be charged in accordance with paragraph 1 and the criteria set out in the delegated act referred to in paragraph 7 shall be set in:

(a) an implementing act, which provides for an annual indexation mechanism and is adopted by the Commission every 5 years in accordance with the examination procedure referred to in Article 136(3); or

(b) in the absence of an implementing act referred to in sub-paragraph (a), in accordance with the rules and procedures set out in Article 20 of Regulation XXXX/XXXX [revised UCC].

Article 120

Empowerment of the European Union Customs Authority

1. The Commission entrusts the EU Customs Authority established by Article 229 of Regulation (EU) …/… [nUCC] with the performance of all necessary tasks for the implementation of powers and tasks of the Union referred to in Articles 115 to 118 of this Regulation, whereby the implementation of such powers shall constitute further

tasks of the European Union Customs Authority within the meaning of Article 233 of Regulation (EU) …/… [nUCC].

2. The Commission entrusts the EU Customs Authority established by Article 229 Regulation (EU) …/… [nUCC] with the drafting of the preparatory documents necessary for the purpose of implementing the Union powers and tasks described in Article 115 to 118 of this Regulation, whereby such preparatory tasks shall constitute further tasks of the European Union Customs Authority within the meaning of Article 233 of Regulation (EU) …/… [nUCC].

Chapter 4

MARKET SURVEILLANCE ON PRODUCTS ENTERING THE UNION MARKET

Article 121

Controls on the compliance of products entering the Union Market

1. Customs authorities shall carry out controls on the compliance of products entering the Union market in accordance with the provisions laid down in Regulation XXXX/XXXX [nUCC], in particular, Articles 54 to 70 [customs supervision, customs controls and customs risk management in the nUCC], Article 77 [release of the goods in nUCC], and Articles 94 to 96 [disposal of goods in nUCC], Title VI Chapter 1 [Entry of Goods], thereof. Those provisions shall be complemented by the provisions laid down in this Chapter.

2. In addition to customs authorities, designated in accordance with Article 6 of Regulation XXXX/XXXX [nUCC], Member States may designate one or more market surveillance authorities or any other authority in their territory to carry out controls on the compliance of products entering the Union market. These authorities shall have the necessary powers and resources for the proper execution of these controls in accordance with Regulation XXXX/XXXX [nUCC], and tasks set out in this Regulation. Each Member State designating additional authorities shall inform the Commission and the other Member States thereof, including their areas of competence, through the EU Market Surveillance Data Hub referred to in Article 128.

3. Where appropriate to enhance the effectiveness and efficiency of the controls on the compliance of products entering the Union market in view of the specificities of certain supply chains or customs procedures, customs authorities may carry out the controls on the compliance of products entering the Union market before placing them under a customs procedure other than the release for free circulation, or at the entry of the product in the customs territory of the Union as referred to in Regulation XXXX/XXXX [nUCC], in accordance with the customs risk management framework laid down in accordance to Title IV of Regulation XXXX/XXXX [nUCC].

4. The release of the product shall not be deemed to be proof of compliance with Union law.

5. The Commission shall draw up a report by 30 June of each year assessing the performance of controls on the compliance of products entering the Union market. The report shall be published in the EU Market Surveillance Data Hub and may rely on all the data available in the EU Customs Data Hub, the registry and the EU Market Surveillance Data Hub.

6. The Commission may require the Member States and the EU Customs Authority to submit additional information and statistical data relating to the controls on the compliance of products entering the Union market and necessary for the assessment of the performance referred to in paragraph 1.

Article 122

Compliance Determination Referral

1. Without prejudice to Article 77(3)(c) and (5) of Regulation XXXX/XXXX [nUCC], where they have reasons to believe that a product may not comply with the applicable Union law or may present a serious risks but they deem it appropriate to refer the case to market surveillance authorities to ascertain the non-compliance and serious risks, the authorities referred to in Article 121(1) and Article 121(2) shall suspend the release of the product and immediately notify the case to the market surveillance authorities for a decision.

2. Where the release of a product has been suspended in accordance with paragraph 1, that product shall be released where all the other requirements and formalities relating to such a release have been fulfilled and where either of the following conditions is satisfied:

   (a) within four working days of the date of the suspension, none of the market surveillance authorities notified in accordance with paragraph 1 have not requested to maintain the suspension; or

   (b) all the market surveillance authorities notified in accordance with paragraph 1 informed the authorities referred to in Article 121(1) and Article 121(2) of their approval for release of the product.

3. Where the market surveillance authorities decide that a product referred to in a case notified in accordance with paragraph 1 does not comply with the Union law applicable to it or presents a serious risk, they shall request the authorities referred to in Article 121(1) and paragraph 2 to refuse the release of that product.

4. Where the market surveillance authorities requested the refusal of the release of a product in accordance with paragraph 3, the authorities referred to in Article 121(1) and Article 121(2) shall immediately enter this information in the EU Customs Data Hub referred to in Article 35 of Regulation XXXX/XXXX [nUCC]. Where that product is subsequently declared for another customs procedure or event, those authorities shall also enter this information in the EU Customs Data Hub referred to in Article 35 of Regulation XXXX/XXXX [nUCC] regarding subsequent procedures or events. That information may only be deactivated from the customs procedure and events once the authorities referred to in Article 121(1) and Article 121(2) establish that the non-compliance and serious risks have been solved.

5. A product that does not comply with the applicable Union law or presents a risk to the health and safety of end users or a serious risk may be disposed of, destroyed or abandoned or otherwise rendered inoperable where the authorities referred to in Article 121(1) and Article 121(2) or the market surveillance authorities consider that it is necessary and proportionate to do so.

6. Without prejudice to the provisions laid down in Title V, Chapter 4 of Regulation [nUCC], the cost of any measure taken because of the non-compliance, a risk to the

health and safety of end users or a serious risk of a product shall be borne by the responsible economic operator as established in accordance with this Regulation.

7. The notifications and requests referred to in this Article shall be exchanged between the EU Customs Data Hub and the EU Market Surveillance Data Hub via the technical means of cooperation laid down in Article 128.

Article 123

Exchange of risk information

1. The Commission, the EU Customs Authority referred to in Article 229 of Regulation XXXX/XXXX [nUCC] and customs authorities may process data, including personal and commercially sensitive data, made available by the market surveillance authorities to the extent necessary for enforcing Union law for the purpose and duties set out in the Union customs legislation.

2. Market surveillance authorities shall cooperate with the Commission, the EU Customs Authority referred to in Article 229 of Regulation XXXX/XXXX [nUCC] and national customs authorities for carrying out their duties in accordance with this Chapter, including risk management and, customs controls. This cooperation may include:

   (a) providing the data and the information needed to identify products or economic operators where a high risk of non-compliance has been identified in the EU Market Surveillance Data Hub referred to in Article 128;

   (b) sharing data and information enabling to identify the non-compliance or serious risks of a product or of a category of products, the methods used to circumvent EU law, the actors associated to the supply chain of non-compliant or dangerous products and the actors related to the manufacture, production, supply and distribution of products or any other information relevant for risk management and control purposes through the EU Market Surveillance Data Hub referred to in Article 128;

   (c) contributing to and following legislative developments in policy areas of relevance for customs;

   (d) developing coherent and coordinated supervision strategies for customs risk management;

   (e) facilitating operational implementation, including by supporting the development of joint operational tools and the performance of joint controls in accordance with Article 267 of Regulation (EU) XXXX/XXXX [nUCC];

   (f) where appropriate, exchanging skills and best practices through joint training sessions on how to detect non-compliant products;

   (g) in areas relevant for customs, to contributing to innovation and research activities, to develop new technologies and to facilitate joint procurement.

3. Authorities referred to in Article 121(1) and Article 121(2) shall transfer information relevant to the determination of compliance of a product which has been made as part of controls referred to in Article 121(1), Article 121(2), and Article 121(3) to the EU Market Surveillance Data Hub.

4. The Commission may adopt implementing acts to specify elements of cooperation which require actions from both customs and market surveillance authorities, with a view to ensure a consistent, strengthened and effective level

of controls on products entering the Union market, in accordance with with the cooperation scheme referred to in Article 268 of Regulation XXXX/XXXX [nUCC] and with the customs risk management framework of Title IV of Regulation XXXX/XXXX [nUCC]. The elements of cooperation to be specified may include benchmarks and techniques for controls, elements related to the nature and type of controls, and the organisation of specific cooperation mechanisms. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 136(3).

Article 124

Customs controls relating to the Digital Product Passport and the Product Responsibility Record

1. Products entering the Union market that fall within the scope of Union harmonisation legislation shall be subject to verifications and other measures laid down in this Article.

2. Any person intending to place under the customs procedure 'release for free circulation' a product for which a digital product passport is required pursuant to this Regulation or other applicable Union legislation shall provide or make available to the customs authorities the unique registration identifier of that product, as referred to in Article 82.

3. Any person intending to place under the customs procedure 'release for free circulation' a product for which a product responsibility record is required pursuant to this Regulation or other applicable Union legislation shall provide or make available to the customs authorities the product responsibility identifier of that product as referred to in Article 83.

4. Customs authorities may release a product for free circulation only after having verified that the information listed in paragraph 5 was provided or made available, and that the information referred to in paragraph 5, point (a) to paragraph 5, point (c) corresponds to the data stored in the registry. That verification shall take place electronically and automatically via an interconnection with customs systems as of the date on which the interconnection is operational.

5. The information referred to in paragraph 4 shall consist at a minimum of the:

   (a) commodity code; and

   (b) the unique registration identifier as provided for in paragraph 2; or

   (c) the product responsibility identifier as provided for in paragraph 3; or

   (d) as provided for in Article 109 of Regulation (EU) XXXX/XXXX [nUCC, scope and effect] the identity of the manufacturer established in the Union or the importer established in the Union acting as the responsible economic operator established in the Union as referred to in Article 9.

6. The Commission and customs authorities may retrieve and use the data included in the digital product passport and the registry for carrying out their duties pursuant to Union law, including risk management, customs controls and release for free circulation in accordance with Regulation (EU) XXXX/XXXX [nUCC].

Article 125

Removal from online marketplaces of content referring to a non-compliant or dangerous product

The authorities referred to in Article 121(1) and Article 121(2) shall have the power to require the providers of online marketplaces, manufacturers, importers, authorised representatives, or refurbishers to remove content referring to a non-compliant or dangerous product and referring to products sharing the same identifiers as that product, from an online interface or to require the explicit display of a warning to consumers and other end users when they access the online interface.

Article 126

Technical means of cooperation

1. The Commission shall develop and operate the technical means of cooperation in accordance with Article 50 of Regulation (EU) XXXX/XXXX [nUCC] to enable, as necessary for the performance of the controls of the compliance of products entering the Union market laid down in this Chapter or under Regulation (EU) XXXX/XXXX [nUCC], the automated exchange of information, interoperability and connection of the registry and the EU Market Surveillance Data Hub with the EU Customs Data Hub referred to in Article XX of Regulation (EU) XXXX/XXXX [nUCC] and, where appropriate, other customs systems.
2. The interconnection established pursuant to Article 15(3) of Regulation (EU) 2024/1781 may be part of these technical means and continue to operate for the purposes of this Regulation.
3. The Commission may adopt implementing acts in accordance with Article 136(3) with a view to establish the implementation arrangements and transitional measures for this Article, including the transition measures and confidentiality and data protection aspects necessary for this chapter.

Chapter 5
INTEROPERABLE DIGITAL TOOLS FOR MARKET SURVEILLANCE

Article 127

Digital and Artificial Intelligence Tools

1. The Commission shall develop existing and new digital tools, such as webcrawlers, including those making use of on artificial intelligence and related technologies, and maintain them to facilitate more effective and efficient market surveillance of products under this Regulation, in particular with a view to support the:
   (a) identification of potentially non-compliant products;
   (b) identification of products found to be non-compliant;
   (c) identification of the reappearance of non-compliant products;
   (d) identification of the responsible economic operator established in the Union for a product; and
   (e) collection of real-time data on products.

2. The Commission shall in particular ensure that digital tools, such as webcrawlers, enable:

(a) the transmission of notices within the meaning of Article 16 of Regulation (EU) 2022/2065 from market surveillance authorities to the providers of online marketplaces and economic operators using online interfaces concerning online content referring to non-compliant products;

(b) the automatic transmission of information from the Commission to the providers of online marketplaces and economic operators using online interfaces referring to online content referring to non-compliant products.

Article 128

EU Market Surveillance Data Hub

1. The Commission shall develop and maintain an EU Market Surveillance Data Hub for the collection, processing, storage, and exchange of information, in a structured form, on issues relating to the enforcement of Union product legislation, with the aim of improving the sharing of data among and between Member States and the Commission including for the purpose of requests for information, providing a comprehensive overview of market surveillance activities, results and trends.

2. The Commission, market surveillance authorities, single liaison offices, the EU Customs Authority referred to in article 229 of the Regulation (EU) XXX/XXX [nUCC], and authorities in accordance with Article 121(1) and Article 121(2) shall have access to the system referred to in paragraph 1. The Commission shall develop and maintain the public user interface of this system, where key information for end-users about market surveillance activities shall be provided.

3. The Commission, market surveillance authorities, single liaison offices, the EU Customs Authority referred to in Article 229 of Regulation XXX/XXX [nUCC], and authorities in accordance with Article 121(1) and Article 121(2), may use data collected, processed and stored in the EU Market Surveillance Data Hub for the purpose of enforcing Union or national law in full respect of privacy, the confidentiality of commercially sensitive information and any other grounds of confidentiality recognised under Union law.

4. Market surveillance authorities shall enter into the EU Market Surveillance Data Hub information related to products made available on the market for which a compliance check has been carried out in their territory, including the results of those checks and any corrective action requested. This is without prejudice to Article 25 of Regulation (EU) 2023/988 and Article 122, Article 123(2) and Article 123(3), and Article 126(1) of this Regulation.

5. Single liaison offices shall enter the following information in EU Market Surveillance Data Hub referred to in this Article:

(a) the identity of the market surveillance authorities in their Member State and the areas of competence of those authorities pursuant to Article 84;

(b) the identity of the authorities designated in accordance with Article 121(2);

(c) the national market surveillance strategy drawn up by their Member State in accordance with Article 88 and the results from the review and assessment of the market surveillance strategy.

6. Market surveillance authorities and authorities referred to in Article 121(1) and Article 121(2) may enter into the EU Market Surveillance Data Hub referred to in this article any additional information related to the checks they perform and results of testing carried out by them or at their request.

7. The Commission shall develop and maintain electronic interfaces between the EU Market Surveillance Data Hub and national market surveillance systems. Member States shall link any national market surveillance system with the EU Market Surveillance Data Hub via the electronic interface developed by the Commission, thus ensuring that any information entered into the relevant national market surveillance system is automatically entered into the EU Market Surveillance Data Hub.

8. The Commission shall develop a digital solution allowing the EU Market Surveillance Data Hub to be effectively and efficiently interoperable with all of the following systems such as:

   (a) the European Product Act Registry referred to in Article 81;

   (b) the Customs Data Hub referred to in Article 35 of Regulation XXXX/XXXX [nUCC] or the Customs Risk Management System until Customs Data Hub is fully operational;

   (c) the digital tools referred to in Article 127;

   (d) the Product Safety eSurveillance Webcrawler, referred to in Implementing Regulation (EU) 2024/2639;

   (e) the Safety Gate Rapid Alert System referred to in Article 25 of Regulation (EU) 2023/988;

   (f) the DSA Transparency Database referred to in Article 24 of the Regulation (EU) 2022/2065;

   (g) the Single Reporting Platform referred to in Article 16 of the Regulation (EU) 2024/2847;

   (h) the European Product Registry for Energy Labelling referred to in Article 12 of Regulation (EU) 2017/1369;

   (i) the European Database on Medical Devices referred to in Article 33 of Regulation (EU) 2017/745 and Article 23 of Regulation (EU) 2017/746; and

   (j) other relevant systems used by the Commission for enforcement purposes.

9. The Commission shall ensure that the interoperability between the EU Market Surveillance Data Hub and the systems referred to in paragraph 1 enables the sharing of relevant data between the systems.

10. Market surveillance authorities may notify envisaged corrective action requested in relation to products presenting a serious risk also through the Safety Gate Rapid Alert System if they consider it necessary with regard to the urgency of the risk to the health or safety of consumers.

11. Market surveillance authorities may notify also through the Safety Gate Rapid Alert System of any appropriate action taken or of any corrective action taken by economic operators on the basis of this Regulation and of Union harmonisation legislation in relation to products presenting a less than serious risk.

12. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 136(3) specifying:

(a) the details of implementation arrangements of paragraph 1 to paragraph 7 of this Article with respect to:

   i. how to process information that is collected, stored or exchanged in accordance with paragraph 1 of this Article;

   ii. the information that market surveillance authorities shall enter in the EU Market Surveillance Data Hub in accordance with paragraph 4 of this Article.

(b) the data requirements including data elements to be exchanged between the systems in accordance with this paragraphs 7 and 8 and establishing the technical arrangements necessary to achieve interoperability, including the specifications for a common vocabulary and the logical structures for the exchange of information, as well as the data access rights in accordance with paragraph 8 of this article, if these arrangements are not already set in applicable Union Law.

TITLE VI

MISCELLANOUS AND FINAL PROVISIONS

Chapter 1
FINANCIAL PROVISIONS

Article 129

Financing activities

1. The Union shall finance the performance of the tasks of the Network established in accordance with Article 106(1) and the peer reviews referred to in Article 87.

2. The Union may finance any of the following activities in relation to the application of this Regulation:

   (a) the production and revision of sectoral accreditation schemes referred to in Article 60(2), point (a);

   (b) the activities of the secretariat of the body recognised under Article 61, such as the coordination of accreditation activities, the processing of technical work linked to the operation of the peer evaluation system, the provision of interested parties with information and the participation of the body in the activities of international organisations in the field of accreditation;

   (c) the functioning of the Product Contact Points established under Regulation (EU) 2019/515 of the European Parliament and of the Council;

   (d) the establishment and functioning of Union testing facilities referred to in Article 111;

   (e) the development of instruments of international cooperation referred to in Article 110;

   (f) the drawing up and updating of contributions to guidelines in the fields of accreditation, notification to the Commission of conformity assessment bodies, conformity assessment and on market surveillance;

   (g) the making available to the Commission of technical or scientific expertise for the purpose of assisting the Commission in its implementation of market surveillance administrative cooperation and safeguard clause cases;

   (h) the implementation of national market surveillance strategies referred to in Article 88;

   (i) collaborative activities in accordance with Article 90 and joint actions in accordance with Article 91, including resources and equipment, IT tools and training;

   (j) the performance of preliminary or ancillary work in connection with the implementation of the conformity assessment, metrology, accreditation and market surveillance activities related to the application of Union harmonisation legislation, namely studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits and visit programmes, exchange of personnel,

research work, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work; and

(k) activities carried out under programmes providing technical assistance, cooperation with third countries and the promotion and enhancement of Union conformity assessment, market surveillance and accreditation policies and systems amongst interested parties at Union and international level.

(l) Activities linked to the exercise of the evaluation and monitoring powers referred to in Article 115 and of the direct investigation and enforcement powers referred to in Article 116.

(m) The activities referred to in paragraph 1, point (a) shall be eligible for Union financing only if the Committee set up by Article 2 of Directive (EU) 2015/1535 has been consulted on the requests to be submitted to the body recognised under Article 61 of this Regulation.

3. The Union shall finance the electronic interface referred to in Article 128(8)(b), point (b), including the development of the market surveillance data hub referred to in Article 128 to enable it to receive automatic flows of electronic data from the Customs Data Hub .

4. The Union shall finance the electronic interfaces referred to in Article 128(7) enabling the exchange of data between the market surveillance data hub referred to in Article 121 and the national market surveillance systems.

5. The Union's financial assistance with respect to the activities in support of this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council, either directly, or by entrusting budget implementation tasks to the entities listed in Article 62(1) point (c) of that Regulation.

6. The appropriations allocated to activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.

7. The appropriations determined by the budgetary authority for the financing of market surveillance activities may also cover expenses relating to preparatory work, monitoring, control, audit and evaluation activities which are required for the management of the activities set out in this Regulation and for the achievement of their objectives. These expenses shall include the costs of conducting studies, arranging meetings of experts, information and communication activities, including corporate communication of the political priorities of the Union in so far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange together with all other related technical and administrative assistance expenses incurred by the Commission.

Article 130

Bodies eligible for Union financing

1. Union financing may be granted to the body recognised under Article 61 for the implementation of the activities set out in Article 129.

2. However, Union financing may also be granted to other bodies for the carrying out of the activities set out in Article 129, except those set out in Article 129(2), points (a) and (b).

Article 131

Financing arrangements for accreditation

1. Union financing shall be provided:

   (a) without a call for proposals, to the body recognised under Article 61 to carry out those activities referred to in Article 129(2), points (a), (b), (f), (j) and (k) for which grants can be awarded in accordance with the Financial Regulation;

   (b) in the form of grants after a call for proposals, or by public procurement procedures, to other bodies to carry out the activities referred to in Article 129(2) point (f), (j) and (k).

2. The activities of the secretariat of the body recognised under Article 61 referred to in Article 129(2), point (k) may be financed on the basis of operating grants. In the event of renewal, the operating grants shall not be decreased automatically.

3. Grant agreements may authorise flat-rate cover of the beneficiary's overheads up to a maximum of 10 % of total eligible direct costs for actions, except where the beneficiary's indirect costs are covered through an operating grant financed from the Community budget.

4. The common cooperation objectives and the administrative and financial conditions relating to the grants awarded to the body recognised under Article 61 may be defined in a framework partnership agreement signed by the Commission and that body, in accordance with the Financial Regulation and Regulation (EC, Euratom) No 2018/1046. The European Parliament and the Council shall be informed of the conclusion of any such agreement.

Article 132

Management and monitoring

1. The appropriations determined by the budgetary authority for the financing of conformity assessment, accreditation and market surveillance activities may also cover administrative expenses relating to preparation, monitoring, inspection, auditing and evaluation which are directly necessary for the achievement of the objectives of this Regulation, and in particular studies, meetings, information and publication activities, expenses relating to informatics networks for the exchange of information and any other expenditure on administrative and technical assistance which the Commission may use for conformity assessment and accreditation activities.

2. The Commission shall evaluate the relevance of the conformity assessment, accreditation and market surveillance activities that receive Community financing in the light of the requirements of Community policies and legislation, and inform the European Parliament and the Council of the outcome of that evaluation by *[insert date 5 years after entry into application]* and every five years thereafter.

Article 133

Protecting financial interests of the Union

1. The Commission shall take appropriate measures to ensure that, when activities financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective controls and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.

2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and of on-the-spot inspections, over all grant beneficiaries, contractors and subcontractors who have received Union funds under this Regulation.

3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot controls and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council and Council and Regulation (Euratom, EC) No 2185/96 with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under this Regulation.

4. Cooperation agreements with third countries and with international organisations, contracts, grant agreements and grant decisions resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their respective competences.

Article 134

Union budget

The revenue of the Union shall include the Union fee referred to in Article 147.

Chapter 2
DELEGATED POWERS AND COMMITTEE PROCEDURES

Article 135

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 the delegated acts referred to in this Article shall be conferred on the Commission for a period of five years from *[insert date of entry into application]*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of powers referred to in this Article 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 the principles laid down in the Interinstitutional 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.

6. A delegated act adopted pursuant to this Article shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and 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 […] months at the initiative of the European Parliament or of the Council.

Article 136

Committee procedures

1. The Commission shall be assisted by a committee named the 'European Product Act 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 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act in respect of the implementing powers referred to in Article 100(4), point (b), Article 110(11), Article 111(10) and Article 143(10) of this Regulation, and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Chapter 3
Confidentiality

Article 137

Confidentiality and security rules on the protection of the information received

Without prejudice to national legislation in the area of confidentiality, the safeguarding of confidentiality with regard to the information content shall be ensured. The protection of confidentiality shall not prevent the dissemination to market surveillance authorities of information relevant to ensuring the effectiveness of market surveillance activities.

Article 138

Personal data protection

1. Market surveillance authorities shall perform their activities with a high level of transparency and shall make available to the public any information that they consider to be relevant in order to protect the interests of end users. Market surveillance authorities shall respect the principles of confidentiality and of professional and commercial secrecy and shall protect personal data in accordance with Union and national law.

2. The Commission shall use the data accessed pursuant to this Regulation only for the purpose of monitoring, assessing, and assuring compliance with this Regulation and other Union law and shall take due account of the rights and interests of the economic operators, including the protection of personal data, the protection of confidential information, in particular trade secrets, and maintaining the security of their service.

Chapter 4
Penalties

Article 139

Penalties imposed by the competent authorities of the Member States

1. The Member States shall lay down the rules on penalties applicable to infringements of this Regulation that impose obligations on economic operators, notified bodies and providers of online marketplaces and shall take all measures necessary to ensure that they are implemented in accordance with national law. Such penalties shall be imposed in such way as to ensure that they effectively deprive those responsible of the economic benefits derived from their infringements and to increase in amount for repeated or systemic infringements.

2. The types of infringements by economic operators, notified bodies and providers of online marketplaces subject to penalties shall include at least the following:

   (a) Failure by a manufacturer to carry out the conformity assessment procedure required pursuant to the applicable aligned Union product legislation before placing the product on the market in accordance with Article 12;

   (b) Supply by a manufacturer of a product of incorrect or misleading information in the digital product passport it is required to create in accordance with Article 12;

   (c) Failure by a manufacturer to indicate its name, registered trade name or registered trademark as well as its postal and digital contact on the product or, where that is not possible, on its packaging, in a document accompanying the product or in the digital product passport in accordance with Article 12;

   (d) Failure by a manufacturer to provide the information and documentation requested by a competent national authority or to cooperate with that authority as regards any action taken to eliminate the risks posed by products which they have placed on the market in accordance with Article 12;

   (e) Failure by an importer to take the corrective measures necessary to bring a product it has placed on the market into conformity with this Regulation or the applicable aligned Union product legislation in accordance with Article 13;

   (f) Failure by an importer to provide the information and documentation requested by a competent national authority or to cooperate with that authority as regards any action taken to eliminate the risks posed by products which they have placed on the market in accordance with Article 13;

(g) Failure by an authorised representative to take the corrective measures necessary to bring a product it has placed on the market into conformity with this Regulation or the applicable aligned Union product legislation in accordance with Article 13;

(h) Failure by an authorised representative to provide the information and documentation requested by a competent national authority or to cooperate with that authority as regards any action taken to eliminate the risks posed by products which they have placed on the market in accordance with Article 13;

(i) Failure by an authorised representative to take up, prior to placing a product on the market on behalf of a manufacturer, professional liability insurance in accordance with Article 13;

(j) Failure by a distributor to take the corrective measures necessary to bring a product it has placed on the market into conformity with this Regulation or the applicable aligned Union product legislation in accordance with Article 14;

(k) Failure by a distributor to provide the information and documentation requested by a competent national authority or to cooperate with that authority as regards any action taken to eliminate the risks posed by products which they have placed on the market in accordance with Article 14;

(l) Failure by the economic operator placing a product for which the CE marking is required pursuant to the applicable Union harmonisation legislation on the market to affix that CE marking in accordance with the applicable rules laid down in Articles 18 and 19;

(m) Affixing any misleading markings which may create confusion with respect to the visual identity of the CE marking as laid down in Article 18;

(n) Failure by the economic operator placing a product for which a digital product passport is required pursuant to the applicable Union harmonisation legislation on the market to affix that digital product passport in accordance with Article 17;

(o) Failure by a provider of online marketplace or an economic operator offering products through an online interface to comply with the obligations referred to in paragraphs 1 and 2 of Article 20.

(p) Failure by a conformity assessment body to comply with any of the requirements laid down in Article 22 to Article 49;

3. The penalties provided for shall be effective, proportionate and dissuasive. By *[date of entry into force of this Regulation]*, Member States shall notify the Commission of those rules and of those measures and, without delay, of any subsequent amendments affecting them.

4. Member States shall ensure that the amount of a fine imposed in accordance with paragraph 1 is no less than 1% and no more than 6 % of the annual worldwide turnover of the economic operator or the provider of online marketplace concerned in the preceding financial year.

5. Member States shall ensure that the amount of the fine that may be imposed for the supply of incorrect, incomplete or misleading information and the failure to reply or rectify incorrect, incomplete or misleading information shall be no less than 1 % of the annual income or worldwide turnover of the economic operator or the provider of

online marketplace concerned in the financial year preceding the year in which the fine is imposed.

6. Member States shall ensure that the minimum amount of a periodic penalty payment shall be no less than 5 % of the average daily worldwide turnover or income of the provider of the economic operator or, provided the conditions laid out in Article 20(4) are met, provider of online marketplace concerned in the preceding financial year per day, calculated from the date specified in the decision imposing the periodic penalty payment.

Article 140

Union-level penalties

1. When the Commission takes decisions in accordance with Article 116(4), point (d), it may impose penalties upon the concerned economic operators, notified bodies and providers of online marketplaces for non-compliance with the provisions of this Regulation.

2. The penalties imposed in accordance with paragraph 1 shall be effective, dissuasive and proportionate to the value of the relevant products concerned. Such penalties shall be imposed in such way as to ensure that they effectively deprive those responsible of the economic benefits derived from their infringements and to increase in amount for repeated or systemic infringements.

3. In particular the fines shall be proportionate to the number of non-compliant products placed on the Union market as well as to the nature of the risk associated with the non-compliance. The penalties the Commission imposes in accordance with paragraph 1 shall not exceed 6 % of the annual worldwide turnover of the economic operator or the provider of online marketplace concerned in the preceding financial year calculated from the date specified in the decision concerned.

4. The minimum amount of the fine that the Commission may impose for the supply of incorrect, incomplete or misleading information and the failure to reply or rectify incorrect, incomplete or misleading information shall be no less than 1 % of the annual income or worldwide turnover of the economic operator or the provider of online marketplace concerned in the financial year preceding the year in which the fine is imposed. The minimum amount of a periodic penalty payment that the Commission may impose shall be no less than 5 % of the average daily worldwide turnover or income of the provider of the economic operator or provider of online marketplace concerned in the preceding financial year per day, calculated from the date specified in the decision concerned.

5. The minimum amount of a periodic penalty payment that may be imposed by the Commission shall be no less than 5 % of the average daily worldwide turnover or income of the provider of the economic operator or provider of online marketplace concerned in the preceding financial year per day, calculated from the date specified in the decision concerned.

6. The penalties that the Commission imposes for a given infringement to this Regulation shall not be additional to the penalties imposed by the Member States in accordance with Article 139 for the same infringement.

Article 141

Limitation period for the imposition of Union-level penalties

1. The Commission's power to impose fines in accordance with Article 140 shall be subject to a limitation period of five years.

2. The limitation period provided for in paragraph 1 shall begin to run on the day on which the Commission becomes aware of the non-compliance. However, in the event of continuous or repeated non-compliance, it shall begin to run on the day on which the non-compliance ceases.

3. Any action taken by the Commission or the competent authorities of the Member States for the purposes of ensuring compliance shall interrupt the limitation period.

4. The interruption of the limitation period shall apply for all parties which are held responsible for the participation in the non-compliance.

5. Each interruption shall restart the limitation period. However, the limitation period shall expire, at the latest, on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine. That period shall be extended by the time during which the limitation period is suspended because the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.

Article 142

Limitation period for the enforcement of payment of Union-level penalties

1. The power of the Commission to enforce decisions taken pursuant to Article 140 shall be subject to a limitation period of five years.

2. The limitation period provided for in paragraph 1 shall begin to run on the day on which the decision referred to in paragraph 1 becomes final.

3. The limitation period for the enforcement of payment of fines shall be interrupted:

   (a) by notification of a decision changing the original amount of the fine or refusing an application for that change;

   (b) by any proceedings of the Commission or a Member State, acting at the request of the Commission, brought to enforce the payment of the fine.

4. Each interruption shall restart the limitation period.

5. The limitation period for the enforcement of payment of fines shall be suspended for as long as:

   (a) time to pay is allowed;

   (b) enforcement of payment is suspended pending a decision of the Court of Justice of the European Union on the fine.

Article 143

Right to be heard before the imposition of Union-level penalties

1. Before adopting a decision in accordance with Article 140, the Commission shall give the economic operator concerned the opportunity of being heard on:

(a) preliminary findings of the Commission, including any matter to which the Commission has taken objections;

(b) measures that the Commission might take in view of the preliminary findings referred to in point (a).

2. The economic operators concerned may submit their observations on the Commission's preliminary findings referred to in paragraph 1, point (a), within a time limit which the Commission shall set in its preliminary findings and which may not be less than 21 days.

3. The Commission shall base its decisions only on objections on which the economic operators concerned have been able to comment.

4. The Commission shall fully respect the rights of defence of the economic operator concerned in any proceedings. The economic operator concerned shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of economic operators in the protection of their business secrets. The right of access to the file shall not extend to confidential information and internal documents of the Commission or the authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and the authorities of the Member States. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove a non-compliance.

Chapter 5
AMENDMENTS

Article 144

Amendment to the Ecodesign for Sustainable Products Regulation

Regulation (EU) 2024/1781 is amended as follows:

(a) In Article 7 subparagraph 2 (a) 'Chapter III' is replaced by 'Articles 77 to 97, Article 126(4), Article 100(2), Article 100(3) and Article 95(9) of Regulation (EU) XXXX/XXXX[EPA]'

(b) In Article 27 subparagraph 1 (c) 'Article 9 and the delegated acts adopted pursuant to Article 4, including a back-up copy of the most up-to-date version of the digital product passport stored by a digital product passport service provider in accordance with Article 10(4)' is replaced by 'Articles 77 to 97, Article 126(4), Article 100(2), Article 100(3) and Article 95(9) of Regulation (EU) XXXX/XXXX[EPA]'

(c) In Article 29 subparagraph 2 (c) 'Article 9 and the delegated acts adopted pursuant to Article 4, including a back-up copy of the most up-to-date version of the digital product passport stored by a digital product passport service provider in accordance with Article 10(4)' is replaced by 'Articles 77 to 97, Article 126(4), Article 100(2), Article 100(3) and Article 95(9) of Regulation (EU) XXXX/XXXX[EPA]'.

(d) In Article 42 subparagraph 1 (a) and 1 (b) and paragraph 5'Articles 10 and 11' is replaced by 'Articles 77 to 97, Article 126(4), Article 100(2), Article 100(3) and Article 95(9) of Regulation (EU) XXXX/XXXX[EPA]'.

(e) in Article 2, points (1), (2), (3), (10), (11), (28), (29), (30), (31), (32), (33), (35), (39), (40), (41), (42), (43), (44), (45) and (46) are repealed;

(f) Articles 9 to 14, 41 and 42 are repealed;

(g) Article 15 is repealed.

The matters previously governed by those provisions shall be governed by Article 4, points (11), (12), (13), (34), (35), (36), (37), (38), (43), (46), (44), (24), (6), (7), (8), (15), (17), (18), (19) and (23), Articles 77 to 97, Article 126(4), Article 100(2), Article 100(3) and Article 95(9) of Regulation (EU) XXXX/XXXX[EPA].

Article 145

Amendment to General Product Safety Regulation

Regulation (EU) 2023/988 is amended as follows:

(a) Article 2 is amended as follows:

In paragraph 1, subparagraph 3,'With regard to products subject to specific requirements imposed by Union harmonisation legislation as defined in Article 3, point (27)' is replaced by the following 'With regard to products covered by Part I, of Annex I of Regulation (EU) XXXX/XXXX (EPA)'

(b) Article 16 is amended as follows :

Paragraph 1 is replaced by the following:

"1. A product covered by this Regulation shall not be placed on the market unless there is an economic operator established in the Union who is responsible for the tasks set out in Article 9 of Regulation (EU) XXXX/XXXX [EPA] in respect to that product. Article 7(2) to (4) and Article 9 of that Regulation shall apply to products covered by this Regulation. For the purposes of this Regulation, references to "articles X, Y and Z" in Article 7(3) shall be read as 'articles 9, 10 and 11'.

In paragraph 2, reference to "Article 4(3) of Regulation (EU) 2019/1020" is replaced by 'Article 10 of Regulation (EU) XXXX/XXXX [EPA-]'

(c) Article 10 is amended as follows:

The following paragraphs are added after paragraph 2:

3. "Authorised representatives shall place on the market on behalf of the manufacturer only products complying with this Regulation and the applicable Union product legislation.

4. Before placing a product on the Union market on behalf of the manufacturer, the authorised representatives shall register the digital product passport in the registry in respect of a product for which a digital product passport is required under this Regulation or other Union law and shall ensure the following:

(a) the manufacturer has drawn up the technical documentation referred to in Article 9(2);

(b) the product is accompanied by clear instructions for use and safety or other public interest-related information in a language or languages which can be easily understood by consumers or other end users, as determined by the Member State concerned;

(c) the product is accompanied by instructions for safe refurbishment, according to the relevant Union product legislation, in a language or languages which can be easily understood by consumers or other end users, as determined by the Member State concerned;

(d) when a digital product passport is required by Union product legislation, the manufacturer has created a digital product passport for the product and included all the required information in the digital product passport;

(e) when a digital product passport is required by Union product legislation, the data carrier is affixed in accordance with Article 64 of Regulation (EU) XXX/XXX;

(f) the manufacturer has complied with all requirements set out in this Regulation and in the applicable Union product legislation;

(g) when a digital product passport is required by Union product legislation, the relevant information from the digital product passport has been uploaded in the registry in accordance with Article 81 of Regulation (EU) XXX/XXX.

5. Where authorised representatives consider, or have a reason to believe, that a product is not in conformity with Union product legislation, they shall inform the manufacturer and refrain from placing the product on the market on his or her behalf until it has been brought into conformity.

6. Furthermore, where authorised representatives consider, or have a reason to believe, that a product presents a risk, they shall:

(a) immediately inform the manufacturer thereof ; and

(b) ensure that the market surveillance authorities are immediately informed through the Safety Business Gateway.

7. Authorised representatives shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential or other substantive requirements.

8. When deemed appropriate with regard to the risks presented by a product, authorised representatives shall, to protect the health and safety of consumers, carry out sample testing of marketed products.

9. Where authorised representatives consider, or have a reason to believe, that a product that they have placed on the market on behalf of the manufacturer is not in conformity with the Union product legislation, they shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or to recall it, as appropriate.

10. Furthermore, where the authorised representatives consider, or have a reason to believe, that a product that they placed on the market on behalf of the manufacturer presents a risk, they shall:

(a) immediately inform the manufacturer thereof;

(b) ensure that consumers or other end users are immediately informed thereof in accordance with Article 35 or 36 or both; and

(c) immediately inform the market surveillance authorities through the Safety Business Gateway, giving details, in particular, of the non-compliance and of any corrective measures taken.

11. Authorised representatives shall, for a period of 10 years after the product has been placed on the market on behalf of the manufacturer, keep the unique product identifier of the product at the disposal of the market surveillance authorities and ensure that the technical documentation is accessible in the digital product passport to market surveillance authorities in accordance with Article 10(2).

12. Authorised representatives shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by products which they have placed on the market.

13. Authorised representatives shall take up professional liability insurance up to an amount which is proportionate to their potential maximum exposure which may result from the lack of compliance with their obligations under this Regulation. Upon the request of a market surveillance authority in the context of an investigation, authorised representatives shall present an insurance certificate or other evidence of valid insurance covering products already placed on the market and subject to that investigation.

14. Authorised representatives shall verify whether the manufacturer has made communication channels as referred to in Article 10(12) publicly available to consumers or other end users, in order to allow them to submit complaints concerning the safety of products and provide information on any accident or safety issue they have experienced with the product. If communication channels are not available, authorised representatives shall provide for them, taking into account accessibility needs for persons with disabilities.

15. Authorised representatives shall investigate complaints and information as referred to in paragraph Article 10(13) that they have received via a communication channel made available by the manufacturer and that concern the products that they have made available on the market. Authorised representatives shall file such complaints, as well as recalls and any other corrective measures taken to bring the products into conformity with this Regulation, in the register referred to in Article 10(13), or in their own internal register.

16. Authorised representatives shall keep the manufacturer, distributors and, where relevant, providers of online marketplaces informed in a timely manner of the investigation performed and of the results of the investigation.

17. The internal register referred to in Article 10(13) shall contain only personal data that are necessary for the EU-established economic operator to investigate the complaint or the information referred to in Article 10(13). Such data shall be kept only as long as is necessary for the purposes of the investigation and, in any event, no longer than 5 years after the data have been entered into the internal register.

(d) Article 22 is replaced as follows:

Paragraph 6 is replaced by the following:

6. Providers of online marketplaces shall take into account regular information on dangerous products notified by the market surveillance authorities in line with Article 30 and with Article 81 of Regulation (EU) XXXX/XXX (EPA), received through the Safety Gate Portal and through the EU Market Surveillance Data Hub referred to in Article 128 of Regulation (EU) XXXX/XXX, for the purpose

of applying their voluntary measures aimed at detecting, identifying, removing or disabling access to the content referring to offers of dangerous products on their online marketplace, where applicable, including by making use of the interoperable interface to the Safety Gate Portal in accordance with Article 34 and to the EU Market Surveillance Data Hub referred to in Article 128 of Regulation (EU) XXXXX in accordance with Article 21 of Regulation (EU) XXXXX (EPA). System or to the Market Surveillance Data Hub of any action taken by using the contact details of the market surveillance authority published in the Safety Gate Portal.

Paragraph 7 is replaced by the following:

7. Providers of online marketplaces shall regularly monitor and in any case at least once every seven days, information on dangerous products notified by the market surveillance authorities in line with Article 26, received through the Safety Gate Portal, to detect, identify, remove or disable access to the content referring to offers of dangerous products on their online marketplace, where applicable, including by making use of the interoperable interface to the Safety Gate Portal in accordance with Article 34.

Providers of online marketplaces shall inform the authority that made the notification to the Safety Gate Rapid Alert System of any action taken by using the contact details of the market surveillance authority published in the Safety Gate Portal.

(e) Article 23 is amended as follows:

Paragraph 1 is replaced by:

"Article 15, Article 16, Article 20, Article 21(1) to (6) and (9) to (11), Article 83, and Chapter 1, Chapter 3, Chapter 5, of Title V of Regulation (EU) XXXX/XXXX (EPA) shall apply to products covered by this Regulation".

Paragraph 2 is replaced by:

"2. For the purpose of this Regulation, Article 84 to Article 104 and Article 111 of Regulation (EU) XXXX/XXXX (EPA) shall apply as follows:

(a) reference to "Union harmonisation legislation" in Article 84(6) of that Regulation shall be read as reference to "Union harmonisation legislation or other Union law";

(b) references to 'Union harmonisation legislation', 'applicable Union harmonisation legislation', 'the relevant Union harmonisation legislation' and 'Union harmonisation legislation or other Union law' in Article 85, Article 89, Article 95, Article 91, Article 92, Article 95, Article 96, Article 102, Article 88 of that Regulation shall be read as references to 'this Regulation';

(c) reference to 'that legislation and this Regulation' in Article 85(1), point (b) of that Regulation shall be read as a reference to 'this Regulation';

(d) references to 'Network' shall be read as references to 'Network and Consumer Safety Network referred to in Article 30 of this Regulation';

(e) references to 'non-compliance', 'non-compliances' and 'non-compliant' shall be read as references to 'failure to comply with this Regulation';

(f) the reference to ‘Article 137(3)’ in Article 85(4) of that Regulation shall be read as a reference to ‘Article 85(4) of this Regulation’;

(g) the reference to ‘Article 139’ in Article 92(4), point (m) of that Regulation shall be read as a reference to ‘Article 44 of this Regulation’;

(h) the reference to ‘Article XXX’ in Article 97(1) of that Regulation shall be read as a reference to ‘Article 16 of this Regulation’;

(i) the reference to ‘Articles XX, YY, ZZ’ in Article 97(2) of that Regulation shall be read as a reference to ‘Articles 9, 10, 11, 12 of this Regulation’;

(j) the reference to ‘Article 137(3)’ in Article 111 of that Regulation shall be read as a reference to ‘Article 46(3) of this Regulation’.

(f) Article 44 is amended as follows:

Paragraph 3 is replaced by

“3. The Member States shall, by XX/XX/XXXX, notify the Commission of those rules and of those measures, where they have not previously been notified, and shall notify it, without delay, of any subsequent amendment affecting them”.

After paragraph 3, paragraphs 4 and 5 are added as follows:

4. “Member States shall ensure that the amount of the fines that may be imposed pursuant to paragraph 1 shall be no less than 1% and no more than 6 % of the annual worldwide turnover of the economic operator or the provider of online marketplace concerned in the preceding financial year. Member States shall ensure that the amount of the fine that may be imposed for the supply of incorrect, incomplete or misleading information and the failure to reply or rectify incorrect, incomplete or misleading information shall be no less than 1 % of the annual income or worldwide turnover of the economic operator or the provider of online marketplace concerned in the preceding financial year.

5. Member States shall ensure that the minimum amount of a periodic penalty payment shall be no less than 5 % of the average daily worldwide turnover or income of the provider of the economic operator or, provider of online marketplace concerned in the preceding financial year per day, calculated from the date specified in the decision concerned.”

Article 146

Amendments to Regulation (EC) […] establishing the Union Customs Code and the European Union Customs Authority

Regulation (EC) […] is amended as follows:

(a) Article 233 [Further Tasks] is replaced by the following:

‘(1) The EU Customs Authority may be assigned further tasks in the area of free movement, import and export of third country goods, and in the area of free movement of Union goods, if so provided by relevant Union legal acts. Where such tasks are assigned or entrusted to the EU Customs Authority, appropriate financial and human resources shall be ensured for their implementation.’

(b) In Article 235 [composition of the Management Board]:

(a) paragraphs 3 and 4 are replaced by the following:

‘3. Each member of the Management Board shall have an alternate. The alternate shall represent the member in his/her absence or in the matters related to the field of market surveillance.’

‘4. Members of the Management Board shall be appointed in the light of their knowledge in the field of customs. Alternates to the members of the Management Board shall be appointed in the light of their knowledge in the field of market surveillance. In the appointment of both members and their alternates, due account shall be taken of their relevant managerial, administrative and budgetary skills, and experience with Union customs policy and Union market surveillance policy, respectively. All parties represented in the Management Board shall make efforts to limit turnover of their representatives, in order to ensure continuity of its work. All parties shall aim to achieve a gender-balanced representation on the Management Board.’

(c) In Article 238(1) point (c) [Functions of the management board] is replaced by the following:

‘(c) assess and adopt the consolidated annual activity report on the EU Customs Authority's activities, including an overview of the fulfilment of its tasks and its overall performance in achieving customs policy objectives and market surveillance policy objectives, and send both the report and its assessment by 1 July each year to the European Parliament, the Council, the Commission and the Court of Auditors. The consolidated annual activity report shall be made public;’

(d) In Article 240 [Executive Board] paragraph 4 is replaced by the following:

‘4. The Executive Board, with the aim to ensure gender balance, shall be composed of one of the two representatives of the Commission to the Management Board, three other members appointed by the Management Board from among its members, and one alternate member appointed by the alternates of the Management Board, all with the right to vote. The Executive Board shall elect the Chairperson from among its members. The Executive Director shall take part in the meetings of the Executive Board but shall not have the right to vote. The Deputy Executive Director for field of market surveillance may take part in meetings of the Executive Board, when invited by the Executive Board, and shall not have the right to vote.

(e) In Article 243 [Deputy Executive Director] is replaced by the following:

‘1. The Management Board shall create a post of a Deputy Executive Director to assist the Executive Director in matters related to the field of market surveillance.

2. The Management Board may decide to create a post of a Deputy Executive Director to assist the Executive Director in matters relating to the field of customs.

3. Article 241 shall apply to either post of Deputy Executive Director accordingly.'

Chapter 6
FINAL PROVISIONS

Article 147

Repeal of Decision No 768/2008/EC

Decision No 768/2008/EC is hereby repealed with effect from **XX**. References to the repealed Decision shall be construed as references to this Regulation and shall be read in accordance with the correlation table in the Annex VII to this Regulation.

Article 148

Repeal of Regulation (EC) No 765/2008

Regulation (EC) No 765/2008 is hereby repealed with effect from **XX**. References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in the Annex VII to this Regulation.

Article 149

Repeal of Regulation (EU) 2019/1020

Regulation (EU) 2019/1020 is hereby repealed with effect from **XX**. References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in the Annex VII to this Regulation.

Article 150

Transitional provisions

1. The provisions covered by Title II, Chapter 2 and Chapter 3, Titel III, Chapter 1, Chapter 6, Title III, Chapter 1, Chapter 2, Chapter 3, Chapter 4 and Chapter 5; Title IV, Chapter 1, Article 81 and Article 82 of Chapter 2 of this Regulation shall apply to products covered by each act of aligned Union product legislation from the date on which the relevant act provides for the application of the provisions covered by those Chapters, whether by reference to this Regulation or by means of an amendment to that act.

2. As regards the digital product passport, the provisions of Title IV laying down requirements for the digital product passport infrastructure shall apply, from the date of application of this Regulation, to products already subject to corresponding requirements under Regulation (EU) 2024/1781, in accordance with the correlation table set out in Annex VI. Those provisions shall replace the corresponding provisions of Regulation (EU) 2024/1781 identified in that Annex.

   The remaining provisions of Title IV shall apply to products covered by each act of aligned Union product legislation listed from the date on which the relevant act provides for the application of those provisions, whether by reference to this Regulation or by amendment of that act.

3. By derogation from paragraph 1 of Article 13 of the Regulation (EU) 2019/1020, market surveillance authorities shall not be required to publish a national market surveillance strategy in the **THREE / FOUR years** prior to the date referred to in Article 88(1) of this Regulation.

Article 151

Evaluation and review

1. By **31 December 20XX** and every five years thereafter, the Commission shall carry out an evaluation of this Regulation in light of the objectives that it pursues and shall present a report thereon to the European Parliament, to the Council and to the European Economic and Social Committee.

2. The report shall assess whether this Regulation achieved its objective, in particular with regard to reducing the number of non-compliant products on the Union market, ensuring effective and efficient enforcement of Union harmonisation legislation within the Union, improving cooperation between competent authorities and strengthening the controls on products entering the Union market, while taking into account the impact on business and in particular on SMEs. In addition, the evaluation shall also assess the scope of this Regulation, the effectiveness of the peer review system and of the market surveillance activities that receive Union financing in the light of the requirements of Union policies and law and the possibilities to further improve the cooperation between the market surveillance authorities and customs authorities.

3. Within four years after the first approval of a specific system of product-related pre-export control referred to in Article 110, the Commission shall carry out an evaluation of its effects and cost efficiency.

Article 152

Entry into force and application

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

This Regulation shall apply as from *[insert date 2 years after entry into force]* with the exception of:

(a) Chapter 2 of Title II, Title III, Title IV, which shall apply as from *[insert date 4 years after entry into force]*;

(b) paragraph 1, point (a)(ii) and paragraph 1, point (b)(ii), and in paragraph 2, point (b) of Article 20, which shall apply only after the Commission has adopted the implementing act referred to in paragraph 4 of that Article;

(c) Article 120, which shall apply from 2031 or as from the date the referred to in Article 229 of Regulation XXXX/XXXX [nUCC] fully exercises its tasks in accordance with Regulation XXXX/XXXX [nUCC], whichever the earlier.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council establishing a framework for product compliance, accreditation, and market surveillance and repealing Decision No 768/2008/EC, Regulation (EC) No 765/2008 and Regulation (EU) 2019/1020 (European Product Act)

1.2. Policy area(s) concerned

The proposal concerns the functioning of the internal market for goods, as the effective enforcement of EU product compliance rules provides a level playing field for companies operating within the market and safeguards the health and safety of EU consumers.

1.3. Objective(s)

1.3.1. General objective(s)

The general objective of this Regulation is to improve the functioning of the internal market: i) by laying down the product requirements for the design, conformity assessment and manufacture of products subject to Union harmonisation legislation for the products to be made available on the market while ensuring a high level of public interests, such as the health and safety of persons, in particular consumers and professional users, and, where appropriate, of domestic animals and property, the environment and public security, and any other public interests protected by that legislation and ii) by providing for a framework for the market surveillance of products covered by the Union harmonisation legislation, with a view to ensuring that only compliant products are made available on the Union market.

1.3.2. Specific objective(s)

Specific objective No 1

Providing a future-proof and coherent EU product framework that supports digitalisation, innovation, circularity and sustainability, strengthens conformity assessment and enforcement, and safeguards the free movement of compliant products within the internal market.

Specific objective No 2

Strengthening market surveillance through ensuring a comprehensive and coherent regulatory framework for enforcement, strengthening enforcement capacity and improving cross-border cooperation and coordination.

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposal is expected to substantially reduce the number of non-compliant and unsafe products circulating on the Single Market, thereby improving the protection of consumers and other users by enhancing the health, safety and sustainability of products placed on the Union market. The proposal is expected to strengthen the consistency and effectiveness of the EU product framework by improving the reliability of conformity assessment, facilitating the digital provision of product compliance information and enabling more effective enforcement of Union product

legislation. It is also expected to establish a future-proof horizontal product framework that supports digitalisation, innovation and the transition towards a more circular economy through the wider use of digital compliance information and clearer rules for products throughout their lifecycle. Finally, the proposal is expected to strengthen market surveillance through ensuring a comprehensive and coherent regulatory framework for enforcement, boost enforcement capacity and enhance cross-border cooperation and coordination.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Specific objective No 1 – Providing a future-proof and coherent EU product framework that supports digitalisation, innovation, circularity and sustainability, strengthens conformity assessment and enforcement, and safeguards the free movement of compliant products within the internal market.

(a) Share of compliance checks where authorities can directly access product compliance information

(b) Use of conformity assessment modules for refurbished products

(c) Number of cases involving faulty certificates or repeated noncompliance

(d) Number and duration of safeguard procedures

Specific objective No 2 – Strengthening market surveillance through ensuring a comprehensive and coherent regulatory framework for enforcement, strengthening enforcement capacity and improving cross-border cooperation and coordination.

(a) Number and outcomes of investigations carried out by MSAs

(b) Use of digital tools for market surveillance purposes

(c) Number, type and scale of cooperation activities (e.g., joint actions, clusters' investigations)

1.4. The proposal/initiative relates to:

☑ **a new action**

☐ **a new action following a pilot project/preparatory action** [1]

☑ **the extension of an existing action**

☐ **a merger or redirection of one or more actions towards another/a new action**

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The Regulation should be applicable shortly after its adoption.

Transition period of three years is expected before a full application.

A provisional implementation timeline can be illustrated as follows:

2028: Adoption of the Regulation

[1] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

2028-2031: Planned date of application

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at EU level (ex-ante): The need for EU-level action stems from the inherently cross-border nature of product compliance, safety and enforcement challenges. In this context, EU action delivers clear added value over uncoordinated national measures by enabling a coherent framework for product compliance, conformity assessment and market surveillance, supported by common digital solutions and coordinated enforcement mechanisms operating across the Single Market.

Expected generated EU added value (ex-post): EU-level measures will improve the consistency, comparability, and overall effectiveness of the Union framework for product compliance, conformity assessment and market surveillance, supporting free movement of compliant products and safeguarding a level playing field for EOs. EU action can also generate economies of scale and operational benefits by promoting common approaches, shared digital tools, harmonised conformity assessment practices and structured cooperation mechanisms, including for controls on products entering the Union market. In particular, in view of the increasing number of low-value imports, common digital and systemic tools will enhance the effectiveness, scalability and coordination of investigations carried out by market surveillance authorities.

1.5.3. Lessons learned from similar experiences in the past

Several lessons emerge from the evaluation of the current New Legislative Framework and the Market Surveillance Regulation.

Concerning the New Legislative Framework, the following structural lessons stand out:

(a) The framework needs to be updated to reflect technological developments, including the increasing digitalisation of products, software updates throughout the product lifecycle, and the emergence of circular business models such as remanufacturing.

(b) Conformity assessment procedures need to remain fit for purpose to ensure the compliance of increasingly complex products and to address technological developments throughout the product lifecycle.

(c) The rules governing notified bodies and accreditation need to ensure a consistently high level of competence and reliability of third-party conformity assessment across the Union.

(d) The framework needs to support the digital provision of compliance information and provide sufficient flexibility to respond effectively to crisis situations affecting the placing on the market of products. The framework needs to support the digital provision of compliance information and provide sufficient flexibility to respond effectively to crisis situations affecting the placing on the market of products.

Concerning the Market Surveillance Regulation, the following structural lessons stand out:

(a) Closing existing regulatory gaps and strengthening the powers of market surveillance authorities are essential to ensuring an effective market surveillance system. In particular, evolving supply chains, online sales channels, and the growing presence of non-EU economic operators require authorities to have clear and robust enforcement powers across all distribution channels.

(b) At the same time, regulatory improvements need to be matched by a substantial reinforcement of the operational capacity of market surveillance authorities. Adequate staffing, technical expertise, financial resources, and IT tools are necessary to ensure that authorities can effectively exercise their expanded responsibilities in practice.

(c) While the existing cooperation architecture has demonstrated clear operational value, its effectiveness depends on sustained and structured participation by all actors involved. Continued engagement will be necessary to ensure effective information exchange, coordinated enforcement, and long-term cooperation across Member States.

(d) Finally, additional efforts should be done to collect reliable administrative data on market surveillance, to enable a better analysis of market surveillance in the EU and enforcement at EU level under the MSR and other legislation (e.g. systemic enforcement in the DSA). MSAs need to dispose of a fully digital state-of-the-art tool to record and exchange enforcement information, eliminate reporting duplications, and benefit of interconnection with the EU systems.

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

The proposal will continue to build on actions supported by the Single Market Programme. Complementing those activities, the proposal aims to introduce a Union market surveillance fee, consistent with the Commission's MFF 2028–2034 proposal. The amount of the Union market surveillance fee to be charged per each item of a customs declaration shall be set out by an implementing act, following the adoption of the Regulation.

The proposal is part of the broader EU product legislation framework and operates alongside other acts, such as the General Product Safety Regulation (GPSR), the Union Customs Code (UCC), the Digital Services Act (DSA), the CPC Regulation and the Product Liability Directive (PLD).

1.5.5. Assessment of the different available financing options, including scope for redeployment

The assessment of available financing options has considered the need for additional financing. The introduction of a new fee is envisaged to bring additional resources to reduce pressure on the EU budget and support budget neutrality for most resource-intensive tasks. In addition, redeployment of current staff working on the issues is envisaged to alleviate pressure on EU budget and find efficiency gains. Nevertheless, despite the considerable efforts made by the Commission to redeploy its resources in the past year, to ensure successful delivery and proper implementation of this proposal, an additional reinforcement of Commission staffing will be required to meet the full need.

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

☐ in effect from to [DD.MM]YYYY

☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☑ **unlimited duration**

Implementation with a start-up period from 2028 to 2031,

followed by full-scale operation.

(c) Method(s) of budget implementation planned[(2)]

☑ **Direct management** by the Commission

☑ by its departments, including by its staff in the Union delegations;

☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

☐ third countries or the bodies they have designated;

☐ international organisations and their agencies (to be specified);

☐ the European Investment Bank and the European Investment Fund;

☐ bodies referred to in Articles 70 and 71 of the Financial Regulation;

☐ public law bodies;

☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees;

☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees;

☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

Comments

(2) Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://eceuropaeu.sharepoint.com/sites/budgpedia/SitePages/management-modes-and-bodies.aspx.

Part of EU budget is expected to continue being implemented by EISMEA.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

The Commission shall evaluate the relevance of the conformity assessment, accreditation and market surveillance activities that receive Community financing in the light of the requirements of Community policies and legislation and inform the European Parliament and the Council of the outcome of that evaluation every five years from its entry into force.

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The proposal introduces upgrades to the digital tools and new processes to enhance product compliance. These new rules necessitate the development of IT infrastructure, new EU powers in market surveillance and upgraded coordination between the EU and Member States.

To effectively implement these measures, the Commission's services must be adequately resourced, including:

(a) Technical and operational support for digital infrastructure (e.g., Digital Product Passport, EU Market Surveillance Data Hub, NANDO)

(b) Technical and legal expertise required to exercise EU-level enforcement powers

(c) Coordination with Member States to ensure consistent application of the new legislation.

The implementation of the provisions of the new Regulation is estimated to require 113 Full-Time Equivalents (FTEs) within the Commission, ensuring sufficient capacity for supervision, monitoring, and policy implementation.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

Risks of delays in implementation on Commission or Member States side, leading to non-compliance or fragmented application. Regular engagement with Member States and businesses to identify risks early and align control systems with stakeholder needs.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

The internal control systems in place are effective.

2.3. Measures to prevent fraud and irregularities

The existing fraud prevention measures applicable to the Commission will cover the additional appropriations necessary for this Regulation.

The measures implemented by the Commission will be subject to the ex-ante and ex-post controls in accordance with the Financial Regulation. Contracts and agreements financing the implementation of this Regulation will expressly entitle the Commission, including OLAF and the Court of Auditors to conduct audits, on the spot checks and inspections.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

The estimated impact on expenditure and staffing for 2028 and beyond is added for illustrative purposes only and does not pre-judge the next Multiannual Financial Framework. The source of financing and scope of Union financial commitment in the post-2027 period remain subject to the outcome of interinstitutional negotiations on the MFF 2028-2034 and thereafter shall be determined through the annual budgetary procedure. All appropriations and staffing allocations as of 2028 are indicative.

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff. (3)	from EFTA countries (4)	from candidate countries and potential candidates (5)	from other third countries	other assigned revenue
2	05.03.01.01	Diff.	YES	NO	NO	NO

New budget lines requested

In order of multiannual financial framework headings and budget lines.

(3) Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
(4) EFTA: European Free Trade Association.
(5) Candidate countries and, where applicable, potential candidates from the Western Balkans.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./non-diff.	from EFTA countries	from candidate countries and potential candidates	from other third countries	other assigned revenue
N/A	N/A	N/A	N/A	N/A	N/A	N/A

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

☐ The proposal/initiative does not require the use of operational appropriations

☑ The proposal/initiative requires the use of operational appropriations, as explained below:

(d) *Appropriations from voted budget*

EUR million (to three decimal places)

Heading of multiannual financial framework	Number					2		
DG: GROW	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
Operational appropriations								

Budget line	Commitments	(1a)	49.265	51.265	51.265	47.932	47.932	47.932	45.958	**341.548**
	Payments	(2a)	25.712	46.885	51.265	49.798	48.065	47.932	71.891	**341.548**
Appropriations of an administrative nature financed from the envelope of specific programmes [6]										
Budget line		(3)								**0**
TOTAL appropriations for DG GROW	Commitments	=1a+1b+3	**49.265**	**51.265**	**51.265**	**47.932**	**47.932**	**47.932**	**45.958**	**341.548**
	Payments	=2a+2b+3	**25.712**	**46.885**	**51.265**	**49.798**	**48.065**	**47.932**	**71.891**	**341.548**
			Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
TOTAL operational appropriations	Commitments	(4)	49.265	51.265	51.265	47.932	47.932	47.932	45.958	**341.548**
	Payments	(5)	25.712	46.885	51.265	49.798	48.065	47.932	71.891	**341.548**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0	0	0	0	0	0	0	**0**

(6) Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

TOTAL appropriations under HEADING 2 of the multiannual financial framework	Commitments	=4+6	**49.265**	**51.265**	**51.265**	**47.932**	**47.932**	**47.932**	**45.958**	**341.548**
	Payments	=5+6	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

			Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
TOTAL operational appropriations (all operational headings)	Commitments	(4)	49.265	51.265	51.265	47.932	47.932	47.932	45.958	**341.548**
	Payments	(5)	25.712	46.885	51.265	49.798	48.065	47.932	71.891	**341.548**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0	0	0	0	0	0	0	**0**
TOTAL appropriations Under Headings 1 to 3 of the multiannual financial framework (Reference amount)	Commitments	=4+6	**49.265**	**51.265**	**51.265**	**47.932**	**47.932**	**47.932**	**45.958**	**341.548**
	Payments	=5+6	**25.712**	**46.885**	**51.265**	**49.798**	**48.065**	**47.932**	**71.891**	**341.548**

Heading of multiannual financial framework	**4**	‘Administrative expenditure’ [10]

[10] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

DG: GROW			Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
Human resources			12.119	16.777	21.232	21.232	21.232	21.232	21.232	**135.056**
Other administrative expenditure			0	0	0	0	0	0	0	**0**
TOTAL DG GROW	Appropriations		**12.119**	**16.777**	**21.232**	**21.232**	**21.232**	**21.232**	**21.232**	**135.056**
DG: <.....>			Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
Human resources			0	0	0	0	0	0	0	**0**
Other administrative expenditure			0	0	0	0	0	0	0	**0**
TOTAL DG <.....>	Appropriations		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
TOTAL appropriations under HEADING 4 of the multiannual financial framework		(Total commitments = Total payments)	**12.119**	**16.777**	**21.232**	**21.232**	**21.232**	**21.232**	**21.232**	**135.056**

EUR million (to three decimal places)

		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework	Commitments	**61.384**	**68.042**	**72.497**	**69.164**	**69.164**	**69.164**	**67.190**	**476.604**
	Payments	**37.831**	**63.662**	**72.497**	**71.030**	**69.297**	**69.164**	**93.123**	**476.604**

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇓			Year **2028**		Year **2029**		Year **2030**		Year **2031**		Enter as many years as necessary to show the duration of the impact (see Section 1.6)						**TOTAL**	
	OUTPUTS																	
	Type [16]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total Cost
SPECIFIC OBJECTIVE No 1 [17]: [...]																		
Output																		

[16] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

[17] As described in point 1.4.2. 'Specific objective(s)...'

Output																	
Output																	
Subtotal for specific objective No 1																	
SPECIFIC OBJECTIVE No 2 ...																	
Output																	
Subtotal for specific objective No 2																	
TOTALS																	

3.2.3. Summary of estimated impact on administrative appropriations

☐ The proposal/initiative does not require the use of appropriations of an administrative nature

☑ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

3.2.3.1. Appropriations from voted budget

VOTED APPROPRIATIONS	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
HEADING 4								

Human resources	12.119	16.177	21.232	21.232	21.232	21.232	21.232	**135.056**
Other administrative expenditure	0	0	0	0	0	0	0	**0**
Subtotal HEADING 4	**12.119**	**16.177**	**21.232**	**21.232**	**21.232**	**21.232**	**21.232**	**135.056**
Outside HEADING 4								
Human resources	0	0	0	0	0	0	0	**0**
Other expenditure of an administrative nature	0	0	0	0	0	0	0	**0**
Subtotal outside HEADING 4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
TOTAL	**12.119**	**16.177**	**21.232**	**21.232**	**21.232**	**21.232**	**21.232**	**135.056**

3.2.4. Estimated requirements of human resources

☐ The proposal/initiative does not require the use of human resources

☑ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs) [18]

[18] Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

VOTED APPROPRIATIONS		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**
Establishment plan posts (officials and temporary staff)								
20 01 02 01 (Headquarters and Commission's Representation Offices)		52	71	89	89	89	89	89
20 01 02 03 (EU Delegations)		0	0	0	0	0	0	0
(Indirect research)		0	0	0	0	0	0	0
(Direct research)		0	0	0	0	0	0	0
Other budget lines (specify)		0	0	0	0	0	0	0
External staff (in FTEs)								
20 02 01 (AC, END from the 'global envelope')		19	28	37	37	37	37	37
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0	0	0	0
Admin. Support line [XX.01.YY.YY]	at Headquarters	0	0	0	0	0	0	0
	in EU Delegations	0	0	0	0	0	0	0
(AC, END - Indirect research)		0	0	0	0	0	0	0
(AC, END - Direct research)		0	0	0	0	0	0	0
Other budget lines (specify) - Heading 4		0	0	0	0	0	0	0

Other budget lines (specify) - Outside Heading 4	0	0	0	0	0	0	0
TOTAL	**71**	**99**	**126**	**126**	**126**	**126**	**126**

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 4 should be presented in the designated line.

The appropriations under Headings 1-3 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL MFF 2028-2034**
HEADING 4								
IT expenditure (corporate)	0	0	0	0	0	0	0	**0**
Subtotal HEADING 4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Outside HEADING 4								
Policy IT expenditure on operational programmes	19.190	21.190	21.190	19.190	19.190	19.190	17.217	**136.357**
Subtotal outside HEADING 4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

TOTAL	**19.190**	**21.190**	**21.190**	**19.190**	**19.190**	**19.190**	**17.217**

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

☑ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF).

☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation.

☐ requires a revision of the MFF.

(2) *Third-party contributions*

The proposal/initiative:

☑ does not provide for co-financing by third parties

☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	Total
Specify the co-financing body								
TOTAL appropriations co-financed								

3.3. Estimated impact on revenue

☐ The proposal/initiative has no financial impact on revenue.

☑ The proposal/initiative has the following financial impact:

☑ on own resources

☐ on other revenue

☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative [19]						
		Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**

[19] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

Article								

For assigned revenue, specify the budget expenditure line(s) affected.

[...]

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[...]

1. DIGITAL DIMENSIONS

1.1. Requirements of digital relevance

Reference to the requirement	Requirement description	Actors affected or concerned by the requirement	High-level Processes	Categories
R1 – Art. 17, 64, 65, 81, 82 (Art. 144 amends ESPR)	The common Digital Product Passport (DPP) framework was established by the Ecodesign for Sustainable Products Regulation (ESPR) (EU) 2024/1781. This Regulation modifies and extends that framework (Art. 144) and lays down its operational rules of application (Art. 64), including the minimum content of the DPP (Art. 65). Before placing a product on the	Commission; economic operators; competent national authorities; customs authorities; consumers/end users	Management of registries	Data; Digital Solution(s); Digital Public Service(s)

	market or putting it into service, the responsible economic operator must create the DPP (Art. 17(2)), register it in the European Product Act Registry, associate it with a unique registration identifier (Art. 82), and ensure that it is accessible through a data carrier linked to a persistent unique product identifier. The Commission is to set up and manage the registry and the associated digital product passport web portal (Art. 81).			
R2 – Art. 70, 71, 75, 76	The DPP framework must support the full lifecycle of product information, including post-market updates and the creation of a new DPP where required after substantial modification (Art. 70), transfer to another verified actor, retention for the applicable	Economic operators; digital product passport service providers; Commission	Management of registries	Data; Digital Solution(s); Digital Public Service(s)

	availability period, and deletion of registration data after the relevant period (Art. 71). Continuous availability must be ensured through back-up arrangements (Art. 75) with a digital product passport service provider (Art. 76).			
R3 – Art. 68, 69, 72, 73, 74	The DPP framework must support granularity and traceability (Art. 68), including model-, batch- or item-level passports where required by Union law, as well as links between DPPs for complex products and incorporated components (Art. 69). Data carriers and unique identifiers must comply with the technical design and operation rules (Art. 72), the unique-identifier requirements (Art. 73), and common specifications (Art. 74), and must support	Economic operators; Commission; customs authorities; market surveillance authorities	Management of registries; Market surveillance and monitoring	Data; Digital Solution(s)

	interoperability across product legislation.			
R4 – Art. 12, 13, 66, 67, 73	Manufacturers must create the DPP, affix its visual identity and the data carrier, physically or digitally affix the CE marking in the DPP, and register the DPP in the registry (Art. 12(3), 66, 67(3), 73). Importers and authorised representatives – now subject to a single joint article – must verify that these requirements are fulfilled before placing products on the market (Art. 13).	Economic operators; Commission	Product/service/information registry management	Digital Solution(s); Digital Public Service(s); Data
R5 – Art. 20, 21(1), 81(10)	Providers of online marketplaces must interact with the European Product Act Registry through automated tools. Before allowing a product offer targeting consumers in the Union to be listed, they must verify that the product has a valid DPP where required, or that	Online marketplaces; Commission; consumers/end users; economic operators	Management of registries; Market surveillance and monitoring	Digital Solution(s); Digital Public Service(s); Data

	the responsible Union-based economic operator has a valid product responsibility record where no DPP is required (Art. 20(1)). They must also notify the merchant product identifier to the registry, remove offers after automatic invalidation notifications – which constitute an order to remove within the meaning of Article 9 of the Digital Services Act – and prevent the reappearance of offers sharing the same identifiers (Art. 20(2)–(3)). The registry must support these verifications and notifications by automated technical means that do not require an independent assessment of content (Art. 81(10)). The correspondence-verification obligation applies only once the Commission has			

	adopted the implementing act on the software/operational details (Art. 20(4)); if a marketplace fails to fulfil these obligations for a product with no EU-established responsible operator, it assumes the responsible-economic-operator obligations itself (Art. 20(5)). Providers of online marketplaces must also register with the EU Market Surveillance Data Hub (Art. 21(1)).			
R6 – Art. 81(12)(h), 120, 121–124, 126, 128(8)M	The Regulation requires interoperability between the DPP framework, customs systems and market surveillance systems. The registry must be interconnected with the EU Customs Data Hub (established under the new Union Customs Code) for customs verification of DPP-related data (Art. 121–124, 81(12)(h)), via	Commission; customs authorities; market surveillance authorities; Member States	Customs verification; exchange enforcement data; interconnect systems; transmit risk/compliance data	Data; Digital Solution(s); Digital Public Service(s)

	the technical means of cooperation the Commission must develop under Article 126, which also links the registry and the EU Market Surveillance Data Hub with the EU Customs Data Hub. Pending deployment of the EU Customs Data Hub, this may rely on the existing Customs Risk Management System (Art. 128(8)(b)). Performance of the relevant Union-level tasks is entrusted to the new European Union Customs Authority (Art. 120). The Commission must also develop and maintain the EU Market Surveillance Data Hub (Art. 128), including interconnections with national systems and other Union tools (Art. 128(8)), so that market surveillance and controls on products entering the Union market can rely on			

	structured digital data exchange.			
R7 – Art. 127, 128(8)	The Commission must develop digital and AI-driven tools, such as webcrawlers (Art. 127), to support market surveillance of products made available online and offline, including tools for identifying potentially non-compliant products, identifying reappearances of non-compliant offers, identifying the responsible Union-based economic operator, and collecting real-time data on products. The EU Market Surveillance Data Hub must interoperate with relevant Union systems (Art. 128(8)), including the registry, the EU Customs Data Hub, the Product Safety eSurveillance Webcrawler, the Safety Gate Rapid Alert	Commission; market surveillance authorities; online marketplaces	Artificial Intelligence; Automated detection; Interoperability	Digital Solution(s); Data

	System, the DSA Transparency Database, the Single Reporting Platform under the Cyber Resilience Act, the European Product Registry for Energy Labelling (EPREL) and the European Database on Medical Devices (EUDAMED).			
R8 – Art. 20(3)–(4), 21(5), 95, 107(4), 120, 125	The framework supports digital enforcement against online offers of non-compliant products. Providers of online marketplaces must be able to receive and process orders and notices electronically (Art. 20(3)–(4)) and must act within short statutory deadlines on removal orders (2 working days to act, 4 to report back – Art. 21(5)). The authorities responsible for controls on products entering the Union market, and market surveillance authorities more	Market surveillance authorities; Commission; online marketplaces; information society service providers; customs authorities	Exchange enforcement information	Digital Solution(s); Digital Public Service(s); Data

	generally, may require removal of content, display of warnings, or restriction of access to online interfaces (Art. 125, 95, 107(4)). Removal orders issued through the EU Market Surveillance Data Hub or, for products entering the Union market, by the European Union Customs Authority (Art. 120), constitute an order to remove within the meaning of Article 9 of the Digital Services Act. Safety-related alerts continue to be channelled through the Safety Gate Rapid Alert System, which must interoperate with the EU Market Surveillance Data Hub (Art. 128(8)(d)).			
R9 – Art. 22	Where the applicable conformity assessment procedure requires the involvement of a notified body, manufacturers must	Manufacturers; notified bodies; Commission	Conformity assessment; Management of registries	Data; Digital Solution(s); Digital Public Service(s)

	submit conformity-assessment applications and supporting documentation electronically to the notified body through NANDO (the New Approach Notified and Designated Organisations Information System). Notified bodies must record the outcome in NANDO and upload the relevant certificate, attestation, decision or other conformity assessment document, including any subsequent change of status (Art. 22(2)). Manufacturers must ensure that the notified body's identification number and a NANDO-hosted link to that document are uploaded to the European Product Act Registry (Art. 22(2), 81). The Commission must adopt an implementing act laying down the detailed			

	technical rules for this exchange, including the technical arrangements for linking NANDO to the registry (Art. 22(3), point (f)).			

1.2. Data

Type of data	**Reference to the requirement(s)**	**Standard and/or specification (if applicable)**
DPP registration data, including unique product identifier, relevant unique operator identifiers, unique facility identifier where appropriate, reference to the DPP service provider holding the back-up copy, photographs or pictographic elements, and commodity code for products intended for release for free circulation	R1/R2/R6 – Art. 66, 71, 75, 81	To be stored in the European Product Act Registry in accordance with the Regulation and its implementing acts.
DPP content data, including applicable Union harmonisation legislation, compliance statement, required DPP dataset, language availability, links to related DPPs, and lifecycle information (post-market updates, substantial-modification links, transfer of registration, retention periods, and deletion events)	R1/R2/R3 – Art. 65, 66, 68, 70, 71	Open standards; interoperable, machine-readable, structured, searchable and transferable formats are required. These standards are not yet identified in the Regulation and are to be defined through implementing/delegated acts.
Data carrier information (the unique product, operator and facility identifiers themselves are recorded once, under “DPP registration data” above)	R3/R4 – Art. 72, 73	Must comply, where relevant, with the standards to be listed; detailed technical and life-cycle rules may be supplemented by delegated/implementing acts.

Economic operator data, including name or trade name, unique operator identifier, verified capacity, current status, responsible products or product categories, and active/inactive mandate status where applicable	R1/R5 – Art. 81(3), 83, 85	Identity verification under eIDAS (Regulation (EU) No 910/2014) or equivalent secure electronic means for registration.
Customs verification data	R6 – Art. 121–124	Standards and specifications used by the EU Customs Data Hub and national customs IT systems.
Market surveillance records	R6/R7/R8 – Art. 95, 127–128	To be defined in future implementing acts.
Safety alert and recall data	R8 – Art. 128(8)(d)	Standards and specifications used by the Safety Gate Rapid Alert System under Regulation (EU) 2023/988.
Data relating to AI-supported monitoring and detection	R7 – Art. 127	Operational specifications to be developed by the Commission.
Conformity assessment data (NANDO), including the notified body's identification number and links to certificates, attestations, decisions or other conformity assessment documents, and their status changes	R9 – Art. 22	Existing NANDO data formats, document formats and minimum data set, as further specified via implementing act; the technical arrangements for linking NANDO records to the registry are to be specified in the same implementing act.

Alignment with the European Data Strategy

The updated framework relies on two central Commission-managed data infrastructures: the European Product Act Registry and the EU Market Surveillance Data Hub. Together, they support controlled sharing, verification and reuse of structured product, operator and enforcement data across the Commission, Member States, customs and market surveillance authorities, and, for public subsets, consumers, online marketplaces and other actors. This supports the objectives of the European Data Strategy on data availability, reuse, interoperability and trusted sharing across sectors.

Alignment with the once-only principle

The once-only principle is reflected more clearly in the revised framework. The registry is designed to avoid duplicate submissions of core operator and product-identification data and to reuse registration, mandate and identifier information across the product lifecycle and across obligations under different Union acts requiring a DPP. The framework also requires interoperability with customs and market surveillance systems and foresees links with other Union systems.

Data flows

Type of data	**Reference(s) to the requirement(s)**	**Actors who provide the data**	**Actors who receive the data**	**Trigger for the data exchange**	**Frequency (if applicable)**
DPP registration data	R1 – Art. 81	Economic operator or other entitled actor	Commission (registry controller)	Before placing the product on the market / putting into service	As needed
DPP content data	R1/R2 – Art. 66, 81	Economic operator placing the product on the market or putting it into service	Registry	Before placing the product on the market / putting into service; event-driven for lifecycle updates	As needed / event-driven
DPP registration data (merchant product identifier linkage) – complements, and is distinct from, "Economic operator data" above	R5 – Art. 20(2)	Online marketplace, on the basis of the seller/offer information	Registry	Product listed as part of a targeted offer for distance sales	Event-driven
Customs verification data	R6 – Art. 121–124	European Product Act Registry (registry-held	Customs authorities, via the EU Customs Data	Customs declaration made by the economic	Per customs operation

		DPP/registration data)	Hub interconnection	operator (or its customs representative) for release for free circulation	
Market surveillance records	R6/R8 – Art. 95, 128	Market surveillance authorities / designated authorities	EU Market Surveillance Data Hub; Commission; other authorities	Compliance check, suspension, finding of non-compliance or other enforcement event	Without delay / event-driven
Safety alert and recall data	R8 – Art. 128(8)(d)	Market surveillance authority	Commission and other Member States, via Safety Gate	Measure taken/intended with effects beyond one Member State, or serious-risk product identified	Immediately
Data relating to AI-supported monitoring and detection	R7 – Art. 127	Commission-operated tools	Market surveillance ecosystem / relevant authorities	Detection or matching event	Continuous / event-driven
Conformity assessment data (NANDO)	R9 – Art. 22	Notified body, via NANDO	Registry (via the NANDO-registry link); manufacturer	Completion of a conformity assessment procedure requiring notified-body involvement; subsequent change of	Event-driven

				certificate/document status	

1.3. Digital solutions

Digital solution	Reference(s) to the requirement(s)	Main mandated functionalities	Responsible body	How is accessibility catered for?	How is reusability considered?	Use of AI technologies (if applicable)
European Product Act Registry (digital product passport registry)	R1, R2, R5, R6 – Art. 81	Registration of economic operators and other actors; identity verification; storage of identifiers and required registry data; issue of unique registration identifier; public searchability of defined operator/product-responsibility data; automated support for online marketplace verification;	Commission	Publicly accessible/searchable subset for relevant operator/product-responsibility information; differentiated access rights for authorities and other actors	Reuses identifiers across DPP obligations; supports transfer and lifecycle continuity; interoperable with customs and market surveillance systems	No specific AI function assigned

		customs interconnection				
DPP management IT solution	R1–R4 – Art. 64–73	Product-specific digital compliance information; lifecycle updates; linking across original and new passports; access through a data carrier; support for consumer/end-user, authority, and economic-operator access according to rights. It communicates with the European Product Act Registry through the mandatory registration step: upload of the unique product/operator identifiers and other required	Economic operator responsible for creation; possibly supported by a DPP service provider	Consumers/end users have easy and free access to public DPP data; public access must not enable tracking/automated assessment of users. Market surveillance and other competent authorities verify DPP content both directly via the data carrier affixed to the product and, for registry-held registration/lifecycle data, via the registry; the applicable channel depends on the data category and the authority's access rights.	Common technical framework across Union law; single DPP where multiple legal obligations apply	No

		registration data) and, for subsequent updates, through the interconnection to be specified in the implementing acts intended to keep registry-held registration and lifecycle data synchronised with the DPP content held or referenced by this solution.				
Web portal for DPP data	R1 – Art. 81, 114	Public search and comparison of DPP data consistent with access rights	Commission	Publicly accessible web portal (see accessibility note below)	Reuses DPP data through a common access layer; the legal basis and technical definition of that access layer remain to be further specified in the Regulation/implementing acts,	No

					drawing on Union semantic assets (Core Vocabularies) and on Interoperable Europe (European Interoperability Solutions for public administrations, businesses and citizens) building blocks	
EU Market Surveillance Data Hub	R6, R7, R8 – Art. 128	Collection, processing, storage, and exchange of enforcement information; public user interface; interconnection with national systems and relevant Union systems	Commission	Public user interface provides key information for end users	Interoperable with the registry, the Customs Data Hub, the AI-driven tools, the Safety Gate Rapid Alert System, CRMS2, the DSA Transparency Database, EPREL and EUDAMED	

Safety Gate Rapid Alert System / Safety Business Gateway / Safety Gate Portal	R8 – Art. 128(8)(d); also linked in Art. 12(8)	Serious-risk alerts; product-safety notifications; safety recall and accident reporting channels	Commission / Member States as applicable	Existing public-facing and business-facing interfaces remain relevant	Interconnected with the EU Market Surveillance Data Hub	No
Online marketplace automated verification and removal tools	R5/R8 – Art. 20, 21	Automated pre-listing verification, listing removal after registry notification, prevention of reappearance of offers with the same traceability information functionalities	Online marketplaces, supported by registry functionalities	Consumer-facing product listings must make relevant information accessible, including a mandatory weblink to the DPP where applicable	Relies on registry search tools and automated notifications	May rely on automation; software requirements to be specified by the Commission
AI-driven enforcement tools	R7 – Art. 127	Identification of potentially non-compliant products; detection of reappearance; identification of the responsible economic operator;	Commission	Primarily authority-facing tools; accessibility requirements are not the central design feature of the legal provision	Designed to work with the Data Hub and other Union systems	Yes, explicitly envisaged

		collection of real-time data; transmission of notices to online marketplaces (webcrawlers)				
NANDO (New Approach Notified and Designated Organisations Information System)	R9 – Art. 22	Electronic submission of conformity-assessment applications and documentation to notified bodies; recording by notified bodies of conformity-assessment outcomes, certificates, attestations and decisions; recording of subsequent status changes (amendment, suspension, withdrawal, etc.); public interface on the notification/designation status of	Commission	Publicly accessible interface providing information on notification scope and status of notified/designated bodies; a restricted internal module is available to notified bodies, manufacturers and persons acting on their behalf	Pre-existing Union system, already used across New Legislative Framework sectors, reused rather than duplicated; to be technically interconnected with the European Product Act Registry rather than re-creating conformity-assessment data within the registry itself	No

		conformity assessment bodies; technical link between NANDO records and the European Product Act Registry				

European Product Act Registry

Digital and/or sectorial policy (when these are applicable)	Explanation on how it aligns
AI Act	N/A – not a core legal basis for the registry itself; AI may be used elsewhere in the enforcement architecture, not as a constitutive feature of the registry.
EU Cybersecurity framework	The Commission must ensure secure processing of registry data and compliance with rules on cybersecurity, confidentiality and trade secrets.
eIDAS	Registration is completed only after identity verification by electronic identification and authentication under Regulation (EU) No 910/2014 or equivalent secure electronic means.
Single Digital Gateway and IMI	N/A – no explicit operational role is assigned in the legal act.
Others	Mandatory interconnection with the EU Customs Data Hub for customs verification.

DPP management IT solution

Digital and/or sectorial policy (when these are applicable)	Explanation on how it aligns

AI Act	N/A – not a core legal basis for the registry itself; AI may be used elsewhere in the enforcement architecture, not as a constitutive feature of the registry.
EU Cybersecurity framework	The Commission must ensure secure processing of registry data and compliance with rules on cybersecurity, confidentiality and trade secrets.
eIDAS	Registration is completed only after identity verification by electronic identification and authentication under Regulation (EU) No 910/2014 or equivalent secure electronic means.
Single Digital Gateway and IMI	N/A
Others	Mandatory interconnection with the EU Customs Data Hub for customs verification.

Web portal for DPP data

Digital and/or sectorial policy (when these are applicable)	**Explanation on how it aligns**
AI Act	N/A – not a constitutive feature of this solution.
EU Cybersecurity framework	Data authentication, reliability and integrity must be ensured.
eIDAS	Where DPP service providers are used, back-up and access arrangements follow the same identity-assurance principles as registry access.
Single Digital Gateway and IMI	N/A
Others	Common access layer to be further defined.

EU Market Surveillance Data Hub

Digital and/or sectorial policy (when these are applicable)	**Explanation on how it aligns**
AI Act	The Regulation expressly foresees AI-driven tools operating alongside the Data Hub; AI Act compliance would apply as relevant at implementation stage, but the legal act itself mainly sets functional objectives.
EU Cybersecurity framework	Commission-managed system with restricted access for relevant authorities; confidentiality and personal data protection rules apply.
eIDAS	To be confirmed – authentication modalities for authority access are not yet fully specified.
Single Digital Gateway and IMI	N/A
Others	Interoperates with the DPP registry, EU Customs Data Hub, AI-driven tools, Safety Gate, CRMS2, the DSA Transparency Database, EPREL and EUDAMED.

Safety Gate Rapid Alert System / Safety Business Gateway / Safety Gate Portal

Digital and/or sectorial policy (when these are applicable)	***Explanation on how it aligns***
AI Act	N/A
EU Cybersecurity framework	Governed by the security and confidentiality rules of Regulation (EU) 2023/988.
eIDAS	N/A
Single Digital Gateway and IMI	N/A
Others	Safety-related alerts remain channelled through the existing Safety Gate Rapid Alert System; interoperates with the EU Market Surveillance Data Hub.

Online marketplace automated verification and removal tools

Digital and/or sectorial policy (when these are applicable)	Explanation on how it aligns
AI Act	The Regulation expressly foresees AI-driven tools for market surveillance; AI Act compliance would apply as relevant at implementation stage.
EU Cybersecurity framework	Subject to the same access-restriction and confidentiality rules as the Data Hub it supports.
eIDAS	N/A
Single Digital Gateway and IMI	N/A
Others	N/A

NANDO (New Approach Notified and Designated Organisations Information System)

Digital and/or sectorial policy (when these are applicable)	Explanation on how it aligns
AI Act	N/A
EU Cybersecurity framework	Access rights and technical safeguards are required to ensure the security, integrity and confidentiality of information and documents, including protection of personal data and trade secrets
eIDAS	Identification and authentication of manufacturers, notified bodies and persons acting on their behalf is to be specified by implementing act
Single Digital Gateway and IMI	N/A

Digital and/or sectorial policy (when these are applicable)	Explanation on how it aligns
Others	Pre-existing Union system already used across sectors; to be technically interconnected with the European Product Act Registry via a Commission implementing act

1.4. Interoperability assessment

Digital public service or category of digital public services	Description	Reference(s) to the requirement(s)	Interoperable Europe Solution(s)(NOT APPLICABLE)	Other interoperability solution(s)
European Product Act digital ecosystem (European Product Act Registry, DPP management IT solution, web portal, EU Market Surveillance Data Hub, Safety Gate, online-marketplace and customs interfaces, AI-supported enforcement tools, NANDO)	End-to-end digital ecosystem covering economic-operator registration, identity verification and mandate management; digital product passport creation, lifecycle management and cross-border access; public search and comparison of DPP data; cross-border sharing of enforcement, control and compliance data among market surveillance authorities, designated border-control authorities, Member States and the Commission; automated	R1–R9	To be assessed where relevant at implementation level	eIDAS; EU Customs Data Hub; BRIS (open point); Safety Gate; CRMS2; DSA Transparency Database; EPREL; EUDAMED; NANDO; national market surveillance systems; registry automation/search tools

	online-marketplace verification prior to listing and after invalidation; electronic and automated customs verification of DPP-related data in release-for-free-circulation procedures; recording and linking of notified-body conformity assessment outcomes; and AI-supported detection, matching and monitoring tools supporting enforcement across digital environments.			

Impact of the requirements on cross-border interoperability

Assessment	**Measure(s)**	**Potential remaining barriers (if applicable)**
Alignment with existing digital and sectorial policies.	eIDAS-based identity verification; GDPR/Regulation (EU) 2018/1725 compliance; common DPP framework across Union legislation; mandatory customs interconnection	Technical specifications for some aspects of identifiers, data carriers and system interconnections are to be completed through future delegated/implementing acts
Organisational measures for a smooth cross-border digital public services delivery.	Commission manages the registry and the Data Hub; Member States, customs and competent authorities receive access rights	Practical governance and role allocation, and differences in national system maturity and integration capacity, may still require

	according to role; the Digital Product Passport Coordination Group and the Union Product Compliance Network provide coordination mechanisms	operational guidance and staged rollout during implementation
Measures taken to ensure a shared understanding of the data.	Common identifier model; registry data fields; DPP lifecycle rules; public versus restricted access logic; implementing acts to specify Data Hub data requirements	Some product-specific details, and the detailed vocabularies and logical structures for the Data Hub, may depend on future Union-law requirements or implementing acts
Use of commonly agreed open technical specifications and standards.	DPP data must be based on open standards and interoperable formats; identifier/data-carrier standards are anchored in the Regulation and may be updated by delegated acts; common technical arrangements for Data Hub interoperability (vocabulary, logical structures) are to be set by implementing acts	Sequencing and adoption timeline of the relevant implementing/delegated acts, and alignment with parallel technical work on connected systems (e.g. the build-out of the EU Customs Data Hub under the new Union Customs Code, and the interim reliance on the existing CRMS system pending its deployment), may affect the availability of finalised specifications ahead of the Regulation's application dates

1.5. Measures to support digital implementation

Description of the measure	**Reference(s) to the requirement(s) of digital relevance that it supports**	**Commission role** (if applicable)	**Actors to be involved** (if applicable)	**Expected timeline** (if applicable)
Adopt the implementing act specifying the implementation arrangements for the	R1, R6 – Art. 81(12), 121–124	Commission to adopt implementing act	Commission; Member States; economic operators; customs authorities	As provided by the implementation timeline under the Regulation

European Product Act Registry, including communication of the unique registration identifier and relevant interconnections				
Adopt delegated/implementing acts on identifiers, data carriers, technical operation, digital credentials and, where relevant, DPP service provider requirements	R1–R4 – Art. 72, 73, 74, 76	Commission to adopt delegated/implementing acts as empowered by the Regulation	Commission; Member States; economic operators; DPP service providers	As foreseen in the Regulation
Develop technical and user-experience specifications for the DPP web portal in consultation with Member States and stakeholders, including accessibility testing against the Web Accessibility Directive/European Accessibility Act, and publish onboarding guidance for competent authorities and the public ahead of go-live	R1 – Art. 81, 114	Commission implementation task	Commission; Digital Product Passport Coordination Group; users/stakeholders	As part of DPP infrastructure rollout

Provide technical guidance, reference documentation and a testing/sandbox environment for economic operators and DPP service providers on post-market update, substantial-modification, transfer, retention and deletion workflows, and organise implementation workshops with Member State authorities	R2 – Art. 70, 71	Commission to support through guidance and infrastructure	Commission; economic operators; DPP service providers; Digital Product Passport Coordination Group	As part of DPP framework deployment
Develop and publish technical integration specifications (including APIs) and conduct onboarding support and testing sessions with online marketplaces for pre-listing checks, correspondence checks, invalidation notifications and reappearance-prevention functionalities	R5 – Art. 20, 21, 81(10)	Commission infrastructure and implementation support	Commission; online marketplaces	As part of registry and online-marketplace interface deployment
Provide Member States with technical connection guidance,	R6/R7/R8 – Art. 127, 128	Commission implementation task	Commission; Member States; market	As foreseen by implementing acts

sandbox testing facilities and training for national market surveillance systems ahead of interconnection with the EU Market Surveillance Data Hub, and organise coordination workshops through the Union Product Compliance Network			surveillance authorities; customs authorities	
Adopt implementing acts establishing technical arrangements for interoperability between the EU Market Surveillance Data Hub and other Union systems, and develop the technical means of cooperation with the EU Customs Data Hub	R6/R7 – Art. 126, 128	Commission to adopt implementing acts and develop technical means of cooperation	Commission; Member States; relevant Union system owners	As foreseen in the Regulation
Pilot AI-driven detection tools with a subset of market surveillance authorities, provide training on their use and limitations, and publish operational guidance on their interaction with the	R7 – Art. 127	Commission implementation task	Commission; market surveillance authorities	Progressive rollout under the Regulation

EU Market Surveillance Data Hub				
Adopt the implementing act laying down the detailed rules and uniform conditions for electronic submission, exchange, recording and management of information and documents through NANDO, including the technical arrangements for linking NANDO to the European Product Act Registry, and provide onboarding guidance for notified bodies and manufacturers	R9 – Art. 22(3)	Commission to adopt implementing act and provide guidance	Commission; notified bodies; manufacturers	As foreseen in the Regulation