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LIMITE

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NOTE

From: To:	Presidency Delegations
- Presidency partial compromise proposal	

Delegations will find in the Annex the partial Presidency's compromise text for the above proposal, which will be discussed at the meeting of the Working Party on Technical Harmonisation (Construction Products) on 8 May 2023.

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Harmonised zone and national measures

- 1. This Regulation, and the harmonised technical specifications adopted in accordance with it, jointly establish a harmonised zone. The harmonised zone covers all products subject to harmonised technical specifications. These harmonised technical specifications shall be presumed to be comprehensive, in
 - (a) <u>laying down covering</u> all <u>potential</u> <u>essential characteristics and their assesment</u> <u>methods</u>,
 - (b) specifying all inherent product requirements for products other than those covered by other Union law, and
 - (c) <u>determining the applicable assessment and verification systems</u>.

2. Member States shall respect the harmonised zone in their national laws, regulations other rules or administrative measures action and shall not set additional requirements for prohibit or impede the making available of products covered by it when they are in compliance with this Regulation. Member States shall not lay down essential characteristics and their assessment methods or inherent product requirements other than those set out in the harmonised technical specifications.

The harmonised zone does not affect the right of Member States to specify national requirements for the use of products that are subject to harmonised technical specifications.

Any assessment methods and systems for assessment and verification of such national requirements shall be in accordance with applicable harmonised technical specifications.

Member States shall ensure that the making available on the market of products within the harmonised zone which are in compliance with this Regulation shall not be impeded by rules or conditions imposed by public bodies or private bodies acting as a public undertaking, or acting as a public body on the basis of a monopoly position or under a public mandate.

- 2a. They When complying with the obligations provided for in paragraph 2, Member states shall in particular apply the following in relation to products covered by the harmonised zone:
 - (a) no information, or registration or other requirements other than those laid down in the harmonised zone shall be established;
 - (b) no assessments other than those set out in the harmonised zone shall be made mandatory;
 - (e) unless otherwise specified in applicable harmonised technical specifications accordance with Article 5(3), national law, other rules or administrative action pertaining to the making available of products shall not duplicate or go beyond product requirements specified in accordance with Article 5 or the threshold levels established in accordance with Article 4a(4);
 - (d) national law, other rules or administrative action shall not require more assessments and verifications than those set out in Annex V and shall not extend the scope of the assessments and verifications of Annex V;
 - (d1) no markings attesting conformity with requirements or declared performances in relation to essential characteristics covered by the harmonised zone shall be required other than the CE marking, and any existing provisions requiring references to such markings in national measures shall be withdrawn;

- (e) national laws, <u>regulations</u> other rules or administrative <u>measures</u> action shall replicate and not request more or less than what has been required by respect the threshold levels established in accordance with Article 4a(4);
- (f) national laws, <u>regulations</u> other rules or administrative <u>measures</u> action shall not be based on classes, sub-classes or additional classes other than those established in accordance with Article 4a(4);
- (g) where assessment methods have been established in accordance with Articles 4(2) or 4a or in Article 5(2), national laws, regulations other rules or administrative measures action shall, both for construction works and in relation to the characteristics of or requirements for when regulating the the use of those products within the harmonised zone, not refer to other shall rely on the assessment methods applicable according to this Regulation, and not require more assessments and verifications than those set out in Annex V or modify or complement these assessment methods or select just a part thereof.

This paragraph shall also apply to public tenders or direct attributions of contracts where those public tenders or direct attributions are executed under direct or indirect control of public entities or are executed with reference to public provisions on public tenders or direct attribution of contracts. This paragraph shall also apply to grants or other positive incentives with the exception of fiscal incentives. However, harmonised technical specifications may permit or recommend Member States to link the decisions on the attribution of public tenders, of contracts or of grants or other positive incentives to subclasses or additional classes other than those established in accordance with Article 4(4) where these still relate to environmental performances assessed in accordance with these harmonised technical specifications.

- 3. Member States shall communicate to the other Member States and to the Commission the essential characteristics they require for each product family or category, the respective product requirements and the assessment methods they apply. They shall refer to these essential characteristics, requirements and assessment methods proactively in all fora and on all occasions relevant for the elaboration of harmonised technical specifications. Fora elaborating harmonised technical specifications shall take note of these essential characteristics, requirements and assessment methods. The essential characteristics shall be eovered by harmonised technical specifications to the extent. [Substance moved to article 3a]
- 4. Where a Member State deems it necessary, on imperative grounds of health, safety or protection of the environment, including climate, to establish requirements by regulation or to take administrative measures against products within the harmonised zone in relation to characteristics not laid down in harmonised technical specifications of paragraph 2, it shall notify the Commission thereof, justifying the need for the procedural obligations established and explain the regulatory need it aims to address and provide evidence both for the existence of the regulatory need and the lack of coverage by the harmonised zone and other Union law. Member States shall to that end use the notification procedure under Directive (EU) 2015/1535 while making reference to this paragraph and specifying which elements are part of the measure, where applicable.

The Commission shall reply to the notification within the time limits established in procedure set up under Directive (EU) 2015/1535. The Commission shall within twelve months of the notification either put forward a proposal for authorisation in accordance with paragraph 5 or communicate its grounds for rejecting the national measure.

Upon receipt of a notification in the first paragraph, the Commission shall, irrespective of whether the measure may be authorised or not, submit the matter to the CPR Acquis Expert Group established in accordance with Article 3a for consultations on whether updates to existing construction product performance standards need to be requested.

- 5. The Commission shall, by means of implementing acts, authorise the national measure notified under paragraph 4 where:
 - (a) it ascertains that the <u>notified</u> regulation or administrative measure appears duly justified in the light of imperative grounds of health, safety or protection of the environment, <u>including climate</u> referred to in paragraph 4;
 - (b) the regulatory need is not covered by the harmonised zone or by other Union law;
 - (c) the notified regulation or administrative measure does not discriminate against economic operators of other Member States;
 - (d) the notified regulation or administrative measure is able to cover the respective regulatory need; and
 - (e) the notified regulation or administrative measure does not constitute a disproportionally large obstacle to the functioning of the Union market; and
 - the Commission does not indicate by a letter of intent addressed to the Member
 States its intention to publish or cite, within one year as from the date of notification in accordance with paragraph 4, in the Official Journal the harmonised technical specification or to adopt an act of general applicability covering the respective need.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(2).

On duly justified imperative grounds of urgency relating to human health and safety or the protection of the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(3).

6. Member States shall register all their national regulation, and administrative measures
directly or indirectly influencing the usability of products on their territory, into the Single
Digital Gateway.

- 7. This Regulation does not hinder affect the possibilities for Member States to introduce mandatory deposit-refund systems, or to oblige manufacturers to take back used or not used products directly or via their importers and distributors and to establish obligations regarding the collection and the treatment of products for waste, provided that all of the following is complied with:
 - (a) the owner of the product, whilst having a choice amongst the manufacturer, the importer or the distributor as addressee, is in charge of the transport back to the distributor, importer or manufacturer;
 - (b) economic operators in other Member States are not otherwise directly or indirectly discriminated.
- 8. This Regulation does not affect the possibilities for Member States may to ban the destruction of products taken back in accordance with Article 22(2), point (j) and Article 26 or to make the destruction of these products dependent on their prior making available on a national brokering platform for non-commercial use of products.

Recital (23): In order to improve the legal certainty and to mitigate the fragmentation of the EU market for construction products due to the existence of national requirements and marks, it is necessary to clearly define the area regulated at the EU level, the so-called 'harmonised zone', as opposed to the elements remaining within the remit competence of Member States' national regulatory sphere.

Member States remain competent to lay down provisions on construction works, including on their design and dimensioning. The establishment of the harmonised zone should not affect the right of Member States to specify national requirements on construction works and should not reduce the level of protection already existing and justified in the Member States.

Relationship with other Union law

To avoid double assessment of the same aspects of health, safety or protection of the environment of products, the Commission is empowered to supplement this Regulation by delegated acts adopted in accordance with Article 87 by determining the conditions under which the fulfilment of obligations under other Union law also fulfils certain obligations relating to the assessment of a product's performance or the fulfilment of certain product requirements, including the equivalence of assessment and verification systems required, under this Regulation, where otherwise the same aspect of health, safety or protection of the environment would be assessed in parallel satisified by the fulfilment of obligations under one or more of the legal acts listed in Annex Va this Regulation and other Union law.

The conditions referred to in the first subparagraph shall not allow for product safety levels which are less strict than those established in accordance with this Regulation.

Article 15

Supply of the declaration of performance and of the declaration of conformity

- 1. The manufacturer shall supply by An electronic or paper means a copy of the declaration of performance and of the declaration of conformity shall be supplied with of each product which is made available on the market.
 - However, where a batch of the same product is supplied to a single user, it may be accompanied by a single copy of the declarations.

- 2. Where the declaration is provided by electronic means, the manufacturer shall issue that declaration in a commonly readable, but unamendable electronic format. Alternatively, the manufacturer may use a permalink provided that the permalink and the document accessible via the permalink are unamendable. Commission Delegated Regulation (EU) No 157/2014¹ shall apply under this Regulation.
 - The manufacturer shall supply a A paper copy of the declarations shall be supplied if the recipient requests for such paper copy.
- 3. Declarations may contain permalinks to unamendable environmental product declarations or other unamendable documents containing the requested information if those documents follow the order and structure of the declarations or if a correlation table linking the order of the declarations to the order of these documents is provided together with the permalink.
- 4. The manufacturer shall supply the declaration of performance and the declaration of conformity shall be supplied in the language or the languages required by the Member States where the manufacturer intends to make the product is placed or made available on the market. Another economic operator other than the manufacturer seeking to who makes a product available on the market in another Member State requiring a different language shall make available may supply a translation of the declaration of performance and the declaration of conformity in the languages required by that Member State together with the original, and shall comply with paragraphs 1 and 2.

Commission Delegated Regulation (EU) No 157/2014 of 30 October 2013 on the conditions for making a declaration of performance on construction products available on a website; OJ L-52, 21.2.2014, p. 1.

Obligations of all economic operators

- O. The obligations of economic operators in this Chapter are only applicable in relation to products covered by a harmonised technical specification or CE-marked based on a European technical assessment.
- 1. An economic operator shall take all necessary measures to ensure continued compliance, including of products, with this Regulation. Where non-compliance of the economic operator or of a product has been stated and corrective action has been requested by a market surveillance authority in accordance with Article 70(1), the economic operator shall submit progress reports to that authority until that authority decides that the corrective action can be closed.
- 2. Where diverging statements of non-compliance of an economic operator or of a product and requests for corrective action emanate from authorities of different Member States, an economic operator shall take differentiated measures, subject to where the products are intended to be made available on the market or directly installed. Where this is not possible or where a more severe measure imposed by one Member State encompasses the less severe measure imposed by another, the more severe measure shall be taken. Where these rules do not lead to a clear result, the Member States concerned and the Commission, and, on their request, other Member States shall try to find a common solution and, if need is, adopt an implementing act in accordance with Article 33.

- 3. An economic operator shall, on request of an <u>market surveillance</u> authority, <u>communicate</u> identify any economic operator or other actor to that authority:
 - (a) who has supplied it with a product, including components or replacement parts of products, or services, with relevance for a product, and the quantity of that supply, or who has supplied it with a service covered by this Regulation;
 - (b) to who it has supplied a product, including components or replacement parts of products, or services, with relevance for a product, and the quantity of that supply, or to who it has supplied a service covered by this Regulation;
 - (c) who is involved in financial and other collateral services linked to the making available or direct installation of products.

When identifying the operators referred to in first subparagraph, an economic operator shall inform the authority about to all connected data, including:

- (i) addresses of the operators referred to in the first subparagraph;
- (ii) contact details of these operators;
- (iii) email addresses, websites and social media profiles of these operators;
- (iv) tax and company registration numbers of these operators;
- (v) bank accounts of these operators; and
- (vi) names, addresses, contact details of natural or legal persons acting for those operators.

- 4. An economic operator shall be able to present keep all documentatsion and all information referred to in this Chapter to at the disposal of market surveillance authorities for a period of at least ten years after they have last been in possession or dealing the economic operator supplied or were supplied with the product or service in question, unless they documents or the information have been made are permanently available via the product registration database or system established in accordance with paragraph 5 Article 78.
 - An economic operator It shall present the documentsation and information within 10 days of receipt of a request by the respective authority.
- 5. An economic operator shall provide all the requested data into Once the database or system established in accordance with Article 78 is operational, an economic operator may make the following data or documents within two months after the availableility through of that database or system has been stated in a publication of the Official Journal and bear the fees of registration linked thereto. It shall at least bi-annually verify the correctness of the provided data:
 - (a) the declaration of performance and conformity referred to in Article 11 in the form of a product data sheet;
 - (b) the technical documentation referred to in Article 21(3); and
 - (c) the general information, instructions for use and safety information referred to in Article 21(6).

An economic operator shall register into its respective national system established in accordance with Article 77(5).

An economic operator shall make available to consumers and users communication channels, including telephone numbers, e-mail or dedicated sections of its website and social media page, allowing it to communicate any accident, other incident or safety issue it has experienced with the product.

- <u>Five months after the entry into force of the implementing act referred to in Article 78(X), economic operators shall:</u>
 - (a) before placing a product on the market, ensure that the corresponding data or documents referred to in paragraph 5 have been uploaded in the database or system established in accordance with Article 78;
 - (b) before making a product available on the market in a Member State requiring the data or documents referred to in paragraph 5 points (a) and (c) to be in a different language than what has previously been uploaded, ensure that a translation of the data or documents have been uploaded in the database or system established in accordance with Article 78.

Economic operators may, when fulfilling the obligations in point (a) of the first subparagraph, opt to exclude elements of the technical documentation referred to in Article 21(3) which contain confidential information, information protected by intellectual property rights or commercial secrets.

- 6. An economic operator may inform authorities of any likely infringement of this Regulation it becomes aware of. Where this economic operator considers that non-conforming products present a risk to human safety or to the environment, it shall immediately inform the competent authorities of the Member States in which it made the product available thereof, giving details, in particular, of the non-compliance and of any corrective measures taken.
- 7. An economic operator subject to certification by a notified body or supplying services or parts to manufacturers shall permit notified bodies to have access to its documentation and to its premises to the extent that this is needed for the activities of the notified bodies. It shall produce correct information for notified bodies and shall correct any incorrect information. Moreover, this economic operator shall inform the notified body within one month of all changes that might affect the compliance with this Regulation.
- <u>8.</u> <u>Economic operator shall respect the provisions for products marked as "not for construction" set out in art. 31.</u>

Obligations of manufacturers

- 1. When placing a product covered by a construction product performance standard rendered mandatory to apply in accordance with Article 4(2d) or an implementing act adopted in accordance with Article 4a(1) on the market, The manufacturer shall determine the product type, respecting the boundaries set up therefore by the definition provided in Article 3 point (31). The manufacturer shall ensure that the product's performance in relation to its essential characteristics is assessed. If the product is covered by product requirements adopted in accordance with Article 5(1), the manufacturer shall ensure that the product has also been designed and constructed in accordance with those requirements.
- Where a product's compliance with applicable requirements and its performance in relation to its both mandatory essential characteristics and those essential characteristics intended to be declared and its compliance with applicable requirements have been demonstrated type shall be processed in accordance with the applicable assessment and verification system or systems set out in Annex V₋₂. The manufacturer shall draw up a declaration of performance and a declaration of conformity in accordance with Articles 9 and to Articles 11 to 15 and affix the CE marking in accordance with Articles 16 and 17.

- 2. The manufacturer shall refrain from any claim about the characteristics of a product that is not based on:
 - (a) the assessment method contained in a harmonised technical specification where the relevant characteristic is covered by such; or
 - (b) where no such assessment method exists, an assessment method which represents the most effective and advanced method to achieve an accurate assessment. [moved to article 18(3)]
- The manufacturer shall, as the basis for the declarations of performance and conformity referred to in paragraph 1, draw up a technical documentation describing the declared intended use which shall fall within the scope of the applicable intended use. The technical documentation shall including describe the precise conditions for the product's use and include all the relevant elements necessary to demonstrate performance and conformity, including information on procedures in place according to paragraph 4 and on the application of the system or systems applicable in Annex V.

That technical documentation shall, where applicable, contain the mandatory or facultative calculation <u>substantiating the assessment</u> of <u>a product's</u> environmental, <u>including climate</u> sustainability <u>assessed established</u> in accordance with <u>Article 11(2a) and applicable</u> harmonised technical specifications <u>adopted under this Regulation</u> or <u>with Commission</u> acts adopted under this Regulation.

The second subparagraph shall not apply in case of used, remanufactured or surplus products, unless the economic operator, subject to the obligations of this Article by virtue of Article 26, opts for the application of this Regulation for new products.

4. The manufacturer shall ensure that procedures are in place <u>for products to ensure</u> that <u>are part of</u> series production <u>to</u> maintains the<u>ir</u> declared performance and <u>remain in</u> conformity <u>with this Regulation</u>. Changes in the production process, in product design or in characteristics, and changes in the <u>applicable</u> harmonised technical specifications <u>or harmonised standards</u> by reference to which performance or conformity of a product is declared or by application of which its performance or conformity is verified, shall be adequately taken into account and, in case the product's performance or conformity is affected, shall trigger a re-assessment in accordance with the relevant assessment procedure.

The manufacturer shall, where deemed appropriate with regard to ensuring the accuracy, reliability and stability of the declared performance and of the conformity of a product, carry out sample testing of products placed or made available on the market, <u>investigate</u>, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep importers and distributors informed of any such monitoring.

The procedures referred to in the first subparagraph, the sample tests referred to in the second subparagraph and the application of the applicable system of Annex V shall be described in the technical documentation referred to in paragraph 3.

5. The manufacturer shall ensure that its product bears a manufacturer-specific <u>unique</u> identification code of the product type number and, where available, a batch or serial number. If this is impossible, the required information shall be provided on the packaging, on an affixed tag or, as last resort, in a document accompanying the product.

The manufacturer shall in the same way as set out in the first subparagraph label a product as "Only for professional use" if it is not intended for consumers or other non-professional users. Products not labelled "Only for professional use" shall be deemed to be also intended for non-professional users and consumers in the meaning of this Regulation and the Regulation (EU) ... [Regulation on General Product Safety].

The manufacturer shall, in a visible manner, display to customers before it is bound by a sales contract, including in case of distance selling, the information which shall be labelled pursuant to this Regulation or harmonised technical specifications.

6. When making a product available on the market in a certain Member State, the manufacturer shall ensure that the product is accompanied by general information, instructions for use and safety information as set out in Annex I-D the information set out in harmonised technical specifications and in Annex I Part D in a language determined by the Member State concerned or, in absence of such determination, in a language which can be easily understood by users.

The Commission may, by means of implementing acts determine the format and the way of transmission of information to be provided by the manufacturer in accordance with the first subparagraph.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(2).

- 7. The manufacturer shall upload the data of the declaration of performance, of the declaration of and conformity, the information referred to in paragraph 6 and the technical documentation in the EU product database or system established in accordance with Article 78.
- 8. The manufacturer who <u>considers or</u> has reason to believe that a product which it has placed on the market is not in conformity with <u>its declared performance or in compliance with requirements of</u> this Regulation or <u>harmonised technical specifications</u> adopted in accordance with this Regulation, shall immediately take the necessary corrective measures to bring that product into conformity, or, if appropriate, to withdraw or recall it. If the issue is linked to a supplied component or an externally provided service, the manufacturer shall inform the supplier or service provider and the manufacturer's national competent authority thereof; the latter shall transmit the respective information to the national competent authority responsible for the supplier or service provider and suggest appropriate measures.
- 9. Where the product presents a risk or is likely to present a risk, the manufacturer shall within two working days thereof inform the authorised representative, importers, distributors, fulfilment service providers, and online market places involved in the distribution, as well as the competent national authorities of the Member States in which the manufacturer or to its knowledge other economic operators made the product available. The manufacturer shall, to that effect, provide all useful details and, in particular, specify the type of the non-compliance, the frequency of accidents or incidents and the corrective measures taken or recommended. In case of risks caused by products which have already reached the final user or consumer, the manufacturer shall also alert the media and inform them public about those products and any appropriate measures to eliminate or, if not possible, to reduce the risks. In case of a product presents a "serious risk" in the meaning of Article 3, point (71) the manufacturer shall withdraw and recall the product at their own cost.
- 10. The manufacturer shall be liable for infringement of this Article and of Article 19 in accordance with national law on contractual and extra-contractual liability.

Obligations of authorised representatives

- 1. A manufacturer may appoint, by a written mandate, any natural or legal person established within the Union as a single authorised representative. A manufacturer not established in the Union shall appoint a single authorised representative.
 - The obligations laid down in Article 21(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate, but may become subject to separate contracts between the manufacturer and the authorised representative.
- 2. Authorised representatives shall act with due care in relation to the obligations of this Regulation. They shall be liable for gross negligence or conscious infringement of this Article and of Article 19 in accordance with national law on contractual and extracontractual liability.
- The authorised representative shall perform the tasks specified in the mandate <u>received</u> from the manufacturer. The mandate shall allow the authorised representative to <u>do earry</u> out at least the following tasks and shall give the authorised representative the following rights:
 - (a) keep the declaration of performance and the technical documentation at the disposal of national market surveillance authorities;
 - (b) <u>further to a reasoned request from a competent national authority</u>, provide thate <u>market surveillance</u> authorit<u>yies</u> with all the information and documentation necessary to demonstrate the conformity of the <u>a</u> product with <u>its</u> the declar<u>edation</u> of performance and compliance with other applicable requirements in this Regulation at their reasoned request;

- (c) terminate the contract mandate if where the manufacturer acts contrary to its

 obligations under infringes this Regulation and inform thereof the competent national authorities of the Member States where the product is placed on the market and the national competent authority of his own place of business;
- (d) <u>inform competent national authorities</u> when having reason to believe that a product <u>covered by the mandate</u> in question is non-compliant or presents a risk, inform the <u>national competent authorities of the Member States where the product is placed on the market and the national competent authority of his own place of business thereof; and</u>
- (e) cooperate with the market surveillance competent national authorities, at their request, on any action taken
- to eliminate risks posed by <u>and to remedy non-conformities in</u> products covered by the mandate of the authorised representative; or to remedy non-conformities.

The drawing up of technical documentation shall not form part of the authorised representative's mandate, but may become subject to a separate contract between the manufacturer and the authorised representative.

- 4. The authorised representative shall verify the compliance of the product with requirements regarding marking, labelling, instructions for use, declaration of performance and conformity. The authorised representative shall also verify at a documentary level that the manufacturer satisfies his obligations set out in Article 19(4) to (6), Article 21(1) to (3) and (5) to (7), Article 22(1) and Article 22(2) points (f) and (i), and Article 27(6).
- Sharper an authorised representative considers that there is a non-compliance mentioned in the paragraph 4, the authorised representative shall ask the manufacturer to remedy the non-compliances. The manufacturer shall thereon stop the placing on the market and ask other economic operators involved in the distribution to stop their commercial activities, until the authorised representative regards the infringements as remedied. Where the non-compliances are not remedied within one month whilst products possibly continue to be made available on the market, the authorised representative shall be allowed to terminate his contract with the manufacturer and thereof inform the national competent authorities of the Member States where the products are placed on the market and the national competent authority of his own place of business. The latter shall coordinate joint actions of all competent authorities, unless the national competent authorities agree on another national competent authority to coordinate.

Obligations of importers

- 1. The importer shall place on the Union market only products which are compliant with this Regulation.
- Before placing a product on the market, the importer shall ensure that the product's compliance with applicable requirements and its performance in relation to relevant essential characteristics have been demonstrated by verify at a documentary level that the manufacturer has complied with the obligations set out in accordance with Article 21(1) and (1a)., It shall ensure that the manufacturer has drawn up the technical documentation referred to in Article 21(3), and that the product bears the CE mark, where required, and that the manufacturer has complied with the requirements set out in Article 21(5) to (7) and in Article 22(2), points (f) and (i). It shall be liable for infringement of this Article and of Article 19 in accordance with national law on contractual and extra-contractual liability.
- 2. The importer shall verify that the <u>declared</u> intended use of the product has been precisely and correctly determined by the manufacturer and shall ensure that the product is accompanied by a clear indication of the general information, instructions for use and safety information in accordance with Article 21(6) set out in harmonised technical specifications and in Annex I Part D in a language determined by the Member State concerned which can be easily understood by users. The importer shall, in a visible manner, display to customers before they are bound by a sales contract, including in case of distance selling, the information which shall be labelled pursuant to this Regulation or harmonised technical specifications.

- 3. The importer shall ensure that, while a product is under its responsibility, storage or transport conditions do not jeopardise its conformity with the declaration of performance and conformity or its compliance with other applicable requirements in this Regulation.
- 4. After having assembled all available product information from the manufacturer and the de-installer, the importer shall in particular scrutinise used and remanufactured products, namely with regard to damages or indications for loss of performance or non-compliance and changed mechanical or chemical properties, and assess all risks; when necessary to ensure safety or the protection of the environment, the importer shall reduce the <u>declared</u> intended use or refrain from selling. This obligation shall also apply to used and remanufactured products for which no declaration of performance is mandatory.
- Where an importer considers or has reason to believe that the product is not in conformity with the declaration of performance <u>and conformity</u> or not in compliance with other applicable requirements in this Regulation, the importer shall not place the product on the market until it conforms to the accompanying declaration of performance <u>and conformity</u> and it complies with the other applicable requirements in this Regulation or until the declaration of performance <u>and conformity</u> is corrected. Furthermore, where the product presents a risk, the importer shall inform the manufacturer and the geographically responsible <u>national competent market surveillance</u> authorit<u>iesy</u> thereof.
- 6. The importer shall indicate its name, registered trade name or registered trade mark, its place of business, its contact address and, where available, electronic means of communication on the product or, where that is not possible, on its packaging or in a document accompanying the product.

- 7. The importer shall investigate complaints, and, if necessary, keep a register of complaints, of non-conforming products and of product withdrawals or recalls, and shall keep manufacturers and distributors informed of any such monitoring.
- 7a. Importers who consider or have reason to believe that a product, which they have placed on the market, is not in conformity with its declared performance or not in compliance with other applicable requirements in this Regulation shall immediately take the necessary corrective measures to bring that product into conformity, or, if appropriate, to withdraw or recall it. Furthermore, where the product poses a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.
- 8. The importer selling to final users shall also fulfil the obligations incumbent on distributors.

Obligations of distributors

- 1. When making a product available on the market, the distributor shall act with due care in relation to the obligations requirements of this Regulation. It shall be liable for infringement of this Article and of Article 19 in accordance with national law on contractual and extra-contractual liability.
- 2. When <u>Before</u> making a product available on the market, the distributor shall fulfil the obligations incumbent on importers in accordance with Article 24(1) to (5) whilst references to "placing on the market" shall be understood as "further making available on the market" <u>verify that:</u>
 - (a) the product bears the CE marking, where required;
 - (b) the product is accompanied by the general information, instructions for use and safety information in accordance with Article 21(6) in a language which can be easily understood by end-users in the Member State in which the product is to be made available on the market;
 - (c) the manufacturer and the importer have complied with the requirements set out in Article 21(5) and Article 24(6) respectively.
- 3. The distributor shall ensure that no products are sold to consumers or other non-professional users which are labelled "for professional use only". These products shall, in their premises, online and on paper publicity material, be presented as products for professional use only.

- Where an distributor considers or has reason to believe that the product is not in conformity with its declared performance or not in compliance with other applicable requirements in this Regulation, the importer shall not make the product available on the market until it conforms to its accompanying declaration of performance and conformity and it complies with the other applicable requirements in this Regulation. Furthermore, where the product presents a risk, the distributor shall inform the manufacturer and the responsible market surveillance authorities thereof.
- 5. The distributor shall ensure that, while a product is under its responsibility, storage or transport conditions do not jeopardise the product's conformity with its declared performance or its compliance with other applicable requirements in this Regulation.
- 6. The distributor who consider or have reason to believe that a product, which they have made available on the market, is not in conformity with its declared performance or not in compliance with other applicable requirements in this Regulation shall make sure that the necessary corrective measures to bring that product into conformity, to withdraw or to recall it, if appropriate, are taken. Furthermore, where the product poses a risk, the distributor shall immediately inform the competent national authorities of the Member States in which they have made the product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

Obligation of fulfilment service providers, brokers, and online market places, online sellers, online shops and online search engines

- 1. When contributing to the making available on the market or direct installation of a product, fulfilment service provider or broker shall act with due care in relation to the obligations of this Regulation. It shall be liable for infringement of this Article and of Article 19 in accordance with national law on contractual and extra-contractual liability.
- 2. A fulfilment service provider, online seller or broker shall:
 - (a) display, in a visible manner, to customers before they are bound by a sales contract, including in case of distance selling, the information which shall be labelled pursuant to this Regulation or harmonised technical specifications;
 - (b) verify that the manufacturer has complied with the obligations set out in Article 21(1), (3) and (5) to (7) and Article 22(2), points (f) and (i);
 - (c) fulfil the obligations laid down in Article 24(5), whilst references to "placing on the market" shall be understood as "supporting the making available on the market";
 - (d) eliminate all offers for products which are non-compliant or likely to be risky in the meaning of Article 21(9) last sentence on their own initiative or, within two working days, on request of the market surveillance authorities;
 - (e) inform concerned authorities on the measures taken in accordance with points (b), (c) and (d);

(f) support product withdrawals or recalls, regardless of whether initiated by authorities, the manufacturer, the authorised representative or the importer. In cooperation with the economic operator concerned, the fulfilment service provider or broker shall inform consumers directly of product withdrawals or recalls. It shall keep the concerned authorities informed of any action taken.

3. An online marketplace shall:

- (a) for the purpose of the requirements of Article 31(1) of Regulation (EU) 2022/2065

 [the Digital Services Act], design and organise its online interface in such a way that it allows economic operators to fulfil their obligations under Article 32(1a) of this Regulation third party traders to provide to the customers of these traders any information referred to in paragraph 2, point (a);
- (b) establish a single contact point for direct communication with Member States' authorities in relation to non-compliancet with this Regulation, under-performing or unsafe product. This contact point may be the same as the one referred to in [Article 20(1)] of Regulation (EU) .../... [the General Product Safety Regulation] or [Article 110(1)] of Regulation (EU) 2022/2065 .../... [the Digital Services Act];
- (c) give an appropriate answer without undue delay, and in any event within five working days, in the Member State where the online marketplace operates, to notices related to notification of accidents and other incidents with products received in accordance with [Article 14] of Regulation (EU) [.../...] on a Single Market for Digital Services (Digital Service Act) and amending Directive 2000/31/EC;

- 3a. The cooperation between information society service providers and market surveillance authorities referred to in Article 7(2) of Regulation (EU) 2019/1020 shall, with regard to online marketplaces and for the purposes of this Regulation, include in particular:
 - (d) cooperat<u>ione</u> to ensure effective market surveillance measures, including by abstaining from putting in place obstacles to such measures;
 - (e) information to the market surveillance authorities of any action taken with regard to non-compliance or suspected non-compliance concerning products covered by this Regulation;
 - (f) the establishment of a regular and structured exchange of information on offers

 content that hasve been removed on the basis of this Article by online marketplaces
 on the request of market surveillance authorities;
 - (g) allow online tools operated by market surveillance authorities to access their interfaces in order to identify non-compliant products;
 - (h) upon request of the market surveillance authorities, when the online marketplace or its online sellers have put in place technical obstacles to the extraction of data from their online interfaces, allow those authorities to scrape such data for product compliance purposes based on the identification parameters provided by the requesting market surveillance authorities.

- 4. As far as powers conferred by Member States in accordance to Article 14 of Regulation (EU) 2019/1020 are concerned, Member States shall confer on their market surveillance authorities the power, for all products covered by this Regulation, to order an online marketplace to remove specific illegal content referring to a non-compliant product from its online interface, to disable access to it or to display an explicit warning to end users when they access it. Such orders shall comply with [Article 8(1)] of Regulation (EU) .../... [the Digital Services Act].
- 5. An online marketplace shall take the necessary measures to receive and process in accordance with [Article 8] of Regulation (EU) .../...[the Digital Services Act] the orders referred to in paragraph 4.
- 6. The paragraphs 1 and 2, paragraph 3, points (b) to (i) and paragraphs 4 and 5 shall also apply to manufacturers, importers, distributors or other economic operators offering products online without involvement of an online marketplace ("online shops").
- 7. The paragraph 3, points (d) to (h) shall also apply to online search engines.
- 8. A fulfilment service provider shall ensure that the conditions during warehousing, packaging, addressing or dispatching, do not jeopardise the products' conformity with its declared performance or its compliance with other applicable the requirements set out in this Regulation.

Obligations of suppliers and service providers involved in the manufacturing of products

- 1. A supplier or service provider involved in the manufacturing of products shall:
 - (a) provide to manufacturers, notified bodies and authorities all available information on the environmental sustainability of their supplied component or service;
 - (b) ensure the correctness of such information namely by respecting this Regulation and correct any errors made by communication to all their clients and, if potentially useful, to notified bodies and authorities;
 - (c) permit, in absence of such information, their customers to assess that environmental sustainability on their own expense and support that assessment, namely by giving access to all documents, including those of commercial character, relevant for that assessment;
 - (d) permit notified bodies to verify the correctness of any calculation of the environmental sustainability and support that verification;
 - (e) permit notified bodies to verify the performance and compliance of the supplied component or service and support that verification.
- 2. Where a supplier or service provider has been informed in accordance with the last sentence of Article 21(8), it shall forward that information to his other clients who have, in the last 5 years, received components or services which are identical with regard to the issue in question. In case of a serious risk as defined in Article 3, point (71) or a risk falling under the last sentence of Article 21(9), the supplier or service provider shall also inform the national competent authorities of the Member States where products with that component or manufacturing service have been made available on the market or directly installed; where it cannot identify these Member States, it shall inform all national competent authorities.

Online and other distance sales

- 1. Products offered 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 clients in the Union. An offer for sale shall be considered to be targeted at clients in the Union if the relevant economic operator directs, by any means, its activities to a Member State. Inter alia, an offer shall be considered to be targeted at clients in the Union where:
 - (a) the economic operator uses an official language of a Member State, unless selling to the Union is explicitly excluded by effective means;
 - (b) the economic operator uses the currency of the Member States or a crypto-currency covered by Regulation (EU) [...]² unless, in the latter case, selling to the Union is explicitly excluded by effective means;
 - (c) the economic operator has the used internet domain name registered in one of the Member States or uses an internet domain that refers to the Union or one of the Member States; or
 - (d) the geographical areas to which dispatch is available includes a Member State.

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²— Future Regulation of the European Parliament and of the Council on Markets in Crypto-assets, and amending Directive (EU) 2019/1937, see COM/2020/593 final.

- Where economic operators make products available on the market online or through other means of distance sales, the offer of those products shall clearly and visibly indicate at least the following information:
 - (a) a permalink to, or in case of other means of distance sales the unique identification code of the product-type to help locate, the product registration in the database or system established in accordance with Article 78, where available; and
 - (b) [any applicable traffic light label required by delegated acts referred to in Article XX].
- 2. Member States shall designate a single centralised market surveillance authority responsible for detecting products offered from economic operators outside the Union to clients on their territory online and via other distance sales methods.
- 3. Economic operators or online marketplaces shall give market surveillance authorities access to online interfaces where products covered by this Regulation are made available. If there are technical obstacles to the extraction of data from those online interfaces, the economic operator or online marketplace shall, upon a reasoned request of a market surveillance authority, allow that authority to scrape such data for product compliance purposes on the basis of identification parameters specified in the request.

Implementing acts on economic operators' obligations and rights

Where this is necessary to ensure a harmonised application of this Regulation and only to the extent necessary to prevent diverging practices <u>fragmenting the internal market</u> ereating an uneven playing <u>field</u> for economic operators, the Commission may adopt implementing acts providing details on how to execute the obligations <u>and rights</u> of economic operators contained in this Chapter.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(2).

Article 62

Implementing acts on notified bodies' obligations and rights

Where this is necessary to ensure a harmonised application of this Regulation and no resolution of the dispute of the diverging practices was achieved in the group of notifying and designating authorities, in accordance with Article 49a, and only to the extent necessary to prevent diverging practices fragmenting the internal market leading to unequal treatment of and creating an uneven playing field for economic operators, the Commission may adopt implementing acts providing details on how to execute the obligations of notified bodies contained in Articles 60 and 61.

Those implementing acts shall be adopted in accordance with examination procedure referred to in Article 88(2).

EU construction products database or system

- 1. The Commission is empowered to supplement this Regulation by means of delegated act according to Article 87, by setting up shall adopt an implementing act to establish a Union construction products database or system that builds to the extent possible on the Digital Product Passport established by Regulation (EU) ... [Regulation on ecodesign for sustainable products]. This implementing act shall be adopted in accordance with the examination procedure referred to in Article 88(2).
- <u>1a.</u> The database or system referred to in paragraph 1 shall have the following functionalities:
 - (a) enable economic operators to upload the following data or documents:
 - <u>i)</u> the declarations of performance and conformity referred to in Article 11;
 - ii) the general information, instructions for use and safety information referred to in Article 21(6), and
 - <u>iii)</u> the technical documentation referred to in Article 21(3);
 - (b) store and ensure the protection of the data or documents referred to in point (a) for a period of time to be specified in accordance with paragraph 1b.;
 - (c) make all data or documents referred to in point (a) accessible to competent national authorities;

- (d) make the data or documents referred to in point (a)(i) and (ii) publicly accessible in a machine-readable, structured, searchable, transferable and printable format through an open interoperable data exchange network;
- (e) provide the possibility for economic operators to create permalinks to the data or documents referred to in point (a) which can be used for the fulfilment of information obligations under this Regulation;
- (f) allow economic operators to:
 - i) replace data or documents uploaded by themselves with amended versions so that the amended versions can be accessed in parallel with the original version;
 - <u>alert other economic operators or competent national authorities of incorrect</u> data or documents within the database or system.
- 1b. The technical design and operation of the database or system referred to in paragraph 1
 shall comply with the following requirements:
 - (a) the database or system shall be compatible with the digital product passport registry developed in accordance with Regulation (EU) [ESPR] and fulfil the conditions established in [Article 8(4) of ESPR] for a product group to be exempted from the requirement to have a Digital Product Passport;
 - (b) users of construction products, economic operators, competent national authorities and other relevant actors shall have free access to the database or system;
 - (c) the database or system shall ensure data authentication, reliability and a high level of security and protection against fraud;
 - (d) data or documents uploaded to the database or system shall be stored therein for at least 25 years after they have been uploaded.

- <u>1c.</u> The Commission is empowered to adopt delegated acts in accordance with Article 87 to:
 - (a) supplement this Regulation by specifying the functionalities and requirements under paragraphs 1 and 1a to remedy problems identified with the usage of the database or system or to add functionalities needed to adapt it to the once-only principle in relation to information requirements in other EU law; or
 - (b) amend this Regulation to establish longer periods for storage of data and documents than the storage period provided under paragraph 1b point (d), for specific product families or categories or for certain data or documents, where this is justified based on the service life span of a product or the presumptive information needs of users of used products.
- After the database or system has been fully operational for at least one year, and where economic operators and market surveillance authorities in all Member States have successfully used it as intended, the Commission shall adopt an implementing act to provide for the mandatory use of the database or system by economic operators in accordance with Article 19(5a). This implementing act shall be adopted in accordance with the examination procedure referred to in paragraph 2 of Article 88.
- 2. Economic operators may access all information stored in that database or system which regards them specifically. They may request that incorrect information is corrected.

- 3. The Commission may, by implementing acts give access to this database or system to certain authorities of third countries that apply voluntarily this Regulation or that have regulatory systems for construction products similar to this Regulation provided that these countries:
 - (a) ensure confidentiality,
 - (b) are partners of a mechanism for lawful transfers of personal data compliant with the Regulation (EU) 2016/679³-,
 - (c) commit to engage actively by notifying facts that might trigger the need for action of market surveillance authorities, and
 - (d) commit to engage against economic operators infringing this Regulation from their territory.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(1).

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), *OJ L 119*, *4.5.2016*, *p. 1–88*.

Article 82

International cooperation

- 1. The Commission may, for the purpose of the protection of health, safety or the environment, cooperate, including through the exchange of information, with regulatory authorities of third countries or international organisations in the field of application of this Regulation, such as:
 - (a) <u>exchange of information on</u> enforcement activities and measures related to safety and protection of the environment, including market surveillance;
 - (b) exchange of data of economic operators;
 - (c) <u>exchange of information on</u> assessment methods and product testing;
 - (d) <u>exchange of information on eoordinated</u> product recalls, requests for corrective actions and other similar actions;
 - (e) scientific, technical, and regulatory matters, aiming to improve product safety or the protection of the environment;
 - (f) <u>exchange of information on</u> emerging issues of significant environmental, health and safety relevance;
 - (g) <u>exchange of information on</u> standardisation-related activities;
 - (h) exchange of officials.

The exchange of information pursuant to this paragraph shall respect confidentiality rules and be in accordance with applicable Union law.

- 2. The Commission may provide third countries or international organisations with selected information from the product database or system referred to in Article 78, to the system referred to in Article 77 and to the information exchanged amongst authorities in accordance with this Regulation and receive relevant information on products and on preventive, restrictive and corrective measures taken by these third countries or international organisations. The Commission shall share such information with national authorities, where relevant.
- 3. The information exchange referred to in paragraph 12 may take the form of either:
 - (a) a non-systematic exchange, in duly justified and specific cases; or
 - (b) a systematic exchange, based on an administrative arrangement specifying the type of information to be exchanged and the modalities for the exchange.

Where relevant for Member States, the Commission shall share information received through these exchanges with them.

- 4. The Commission may, by implementing act, give regulatory authorities of third countries that voluntarily apply this Regulation or that have regulatory systems for construction products similar to this Regulation access to or the right to fully participate in one or more of the following:
 - (a) the information and communication system established in accordance with Article 77(1);
 - (b) the Union construction products database or system set up in accordance with Article 78;
 - (c) the training events organized in accordance with Article 80(2).

Access to these programmes shall be granted on the condition that the third country concerned commit to engage against economic operators infringing this Regulation from their territory and ensure confidentiality.

Full participation in these programmes in the database system referred to in Article 78, to the system referred to in Article 77 and to the information exchange amongst authorities set out in Article 80 may be offered open to applicant candidate countries and third countries, provided that their third country's legislation is aligned with this Regulation or and that it they recognises certificates issued by notified bodies or European technical assessments in accordance with this Regulation. Such participation is subject to the fulfilment of the same obligations as for EU Member States according to this Regulation, including notification and follow-up obligations. Full participation in the database or system referred to in Article 78 and to the system referred to in Article 77 shall be based on agreements between the European Union and those countries.

- 5. Where agreements with third countries permit the mutual support in terms of enforcement, Member States may, after consultation of the Commission, use the empowerments set out in Chapter VIII also for action against economic operators acting unlawful in or with respect to third countries, provided that the third countries respect the fundamental values referred to in Article 2 TEU, including the rule of law. Member States may request via the Commission third countries to enforce measures adopted in accordance with Chapter VIII. No cooperation under this Paragraph shall happen where there is no de facto reciprocity or where the Commission raises other concerns, namely with regard to the legal conditions set out in this Article or confidentiality of data.
- 6. Any information exchange under this article, to the extent it involves personal data, shall be carried out in accordance with EU data protection rules. If no adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 has been adopted by the Commission in respect of the third country or international organisation concerned, the information exchange shall exclude personal data. If an adequacy decision for the third country or international organisation has been adopted, the information exchange with that third country or international organisation may contain personal data falling within the scope of the adequacy decision and only to the extent that such exchange is necessary for the sole purpose of the protection of health, safety or the environment.
- 7. The information exchanged pursuant to this Article shall be used for the sole purpose of the protection of health, safety or the environment and respect confidentiality rules.

Article 85

Regulatory status of products

Upon a duly substantiated request of a Member State or on its own initiative, the Commission may, by means of implementing acts, determine whether or not a specific item, or category of items, falls within the definition of 'construction product' <u>as referred to in Article 3(1)</u> or constitute an item referred to in Article 2(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(2) of this Regulation.

Article 89

Electronic applications, decisions, documentation and information

1. All applications from or to notified bodies or TABs and decisions made by these bodies or authorities made in accordance with this Regulation can be provided on paper or in a commonly used electronic format provided that the signature is compliant with Regulation (EU) No 910/2014 and the signing person is entrusted to represent the body or economic operator, according to the law of the Member States or Union law respectively.

2. All documentation required by Article 19(7), Article 21(3), Articles 64 to 66 and Annex V can be provided on paper or in a commonly used electronic format and in a way that permits downloads via unmodifiable links (permalinks).

All information obligations under this Regulation set up by Article 7(3), (4) and (6), Article 19(1), (3), (5) and (6), Article 20(2) and (3), Article 21(6) to (9), Article 22(2), points (f) and (i), Article 23(5), Article 24(6), Article 25(2), Article 26(4), Article 27(2), Article 28 to 39, Article 41(3), Article 44(3), (4), (6) and (7), Article 45(3), Article 46(2), Article 47, article 49(5), Article 50(11), Article 53(1), Article 58(1), Article 59(2), Article 61, Article 70(1), (2), (4) and (6), Article 71(2), Article 72(1), (3) and (5), Article 76, Article 77, Article 78(3), Article 79(2), Article 79(3), Article 80(2), Article 82(1) to (3), (6) and (7) and Article 91 can, unless otherwise stated, be satisfied by electronic means. However, information to be provided in accordance with Annex I Part D and harmonised technical specifications specifying it shall be provided on paper for products not labelled "not for consumers" or "only for professional use". Moreover, consumers may request any other information to be provided on paper. Where the information is provided by electronic means, the information shall be issued in a commonly readable electronic format that makes it possible for the recipient to download and print the information.

Economic operators may fulfil information obligations under this Regulation by providing links to documents which are accessible via an online interface, including documents that can be accessed via the database or system referred to in Article 78. Where a link is provided to a document which has not been uploaded to the database or system, the economic operator shall ensure that the information remain accessible for at least 10 years after the placing on the market of the product concerned.

ANNEX V

Assessment and verification systems (AVS)

The manufacturer shall, in accordance with Article 21(1), be responsible for correctly determineing the product type pursuant to Article 3, point 31, and the corresponding product category on the basis of the applicable harmonised technical specification or European Assessment Document. Where a notified body is involved in assessment and verification, the notified body shall, in accordance with Article 60(1), be responsible for verifying these determinations, including the verification that no identical products items are declared to be of a different type.

- 1. System 1+ Full notified body control including audit sample testing
 - (a) The manufacturer shall carry out:
 - (i) factory production control;
 - (ii) further testing of samples taken at the manufacturing plant in accordance with the prescribed test plan;
 - (iii) verification whether the <u>drawing up of</u> technical documentation contain<u>ings full</u> proof of the correct application of this Regulation with regard to the assessment of performance;
 - (iv) verification whether the drawing up of technical documentation containings full proof of conformity with the applicable product requirements under this Regulation.

- (b) The notified body shall issue the certificate of performance and of conformity on the basis of:
 - (i) confirmation of the correct determination of the product type and of the product category;
 - (ii) an assessment of the performance of the product on the basis of type testing
 (including sampling of the item(s) to be taken as representative of the type), type
 calculation or tabulated values and, in all these cases, review of the documentation of the product;
 - (iii) initial inspection of the manufacturing plant and of factory production control;
 - (iii.a) continuing surveillance, assessment and evaluation of factory production control including periodic inspections to the manufacturing plant;
 - (iv) audit-testing of samples taken before placing the product on the market;
 - (v) full verification of the tasks under paragraphs (a) (iii) and (iv).
- (c) The notified body shall provide continuous surveillance, assessment and evaluation of factory production control. On this occasion, it shall undertake a check of 50 random points falling under the paragraphs (a) (ii) to (iv) and withdraw the certificate in case it detects more than 2 non-compliances or one particularly grave non-compliance, amongst these 50 points and the other verifications to be made in accordance with this paragraph.

- 2. System 1 Full notified body control without audit sample testing
 - (a) The manufacturer shall carry out:
 - (i) factory production control;
 - (ii) further testing of samples taken at the manufacturing plant by the manufacturer in accordance with the prescribed test plan;
 - (iii) verification whether the <u>drawing up of</u> technical documentation containings full proof of the correct application of this Regulation with regard to the assessment of performance;
 - (iv) verification whether the drawing up of technical documentation containings full proof of conformity with the applicable product requirements of under this Regulation.
 - (b) The notified body shall issue the certificate of performance and of conformity on the basis of:
 - (ai) confirmation of the correct determination of the product type and of the product category:
 - (ii) an assessment of the performance of the product on the basis of type testing
 (including sampling of the item(s) to be taken as representative of the type), type
 calculation or tabulated values and, in all these cases, review of the documentation of the product;
 - (iii) initial inspection of the manufacturing plant and of factory production control;
 - (iii.a) continuing surveillance, assessment and evaluation of factory production control including periodic inspections to the manufacturing plant;
 - (iv) full verification of the tasks under paragraphs (a) (iii) and (iv).

- (c) The notified body shall provide continuous surveillance, assessment and evaluation of factory production control. On this occasion, it shall undertake a check of 40 random points falling under the items (a) (ii) to (iv) and withdraw the report or certificate in case it detects more than 2 non-compliances or one particularly grave non-compliance, amongst these 40 points and the other verifications to be made in accordance with this paragraph.
- 3. System 2+ Notified body focusing on the factory production control
 - (a) The manufacturer shall carry out:
 - (i) an assessment of the performance of the product on the basis of testing (including sampling of the item(s) to be taken as representative of the type), type calculation, tabulated values or descriptive documentation of that product;
 - (ii) factory production control;
 - (iii) testing of samples taken at the factory in accordance with the prescribed test plan;
 - (iv) verification whether the drawing up of technical documentation containings full proof of the correct application of this Regulation with regard to the assessment of performance;
 - (v) verification whether the drawing up of technical documentation containings full proof of conformity with the applicable product requirements of under this Regulation.

- (b) The notified body shall issue the certificate of conformity of the factory production control on the basis of:
 - (i) confirmation of the correct determination of the product type and of the product category and confirmation of the correct assessment of the performance of the product on the basis of the review of the documentation of the product;
 - (ii) initial inspection of the manufacturing plant and of factory production control;
 - (ii.a) continuing surveillance, assessment and evaluation of factory production control including periodic inspections to the manufacturing plant;
 - (iii) full verification of the tasks under paragraphs (a) (iv) and (v).
- (e) The notified body shall provide continuous surveillance, assessment and evaluation of factory production control. On this occasion, it shall undertake a check of 30 random points falling under the paragraphs (a) (iii) to (v) and withdraw the certificate in case it detects more than 2 non-compliances or one particularly grave non-compliance, amongst these 30 points and the other verifications to be made in accordance with this paragraph.

- 4. System 3+ Notified body's control of environmental sustainability assessments based on data models
 - (a) The manufacturer shall carry out:
 - (i) the assessment of the performance of the product <u>on the basis of data collection for</u>
 <u>input values, assumptions and modelling in relation to essential characteristics or</u>
 <u>product requirements related to environmental sustainability and keep it updated;</u>
 - (ii) factory production control.
 - (b) The notified body shall <u>in issue a validation report</u>, in particular in view of <u>the assessment</u> on the basis of:
 - (0) <u>validation of the</u> input values, assumptions made and compliance with applicable generic or product category specific rules:
 - (i) <u>validation of verify</u> the manufacturer's <u>initial and updated</u> assessment;
 - (ii) validatione of the process applied to generate that assessment;
 - (iii) validation of the software used for the assessment;
 - [(iv) initial inspection of the manufacturing plant to validate any company-specific data].

(c) Validation shall include verification of all calculations and verification of 10 samples of eompany specific or secondary data factored in, with zero tolerance for incorrectness. In that context, the notified body shall verify whether the applicable rules on modelling and ealculation laid down in the applicable harmonised technical specification or methodology provided by the Commission are followed.

In case an IT tool provided by the Commission is used, the verification focuses on the correct use of the tool. Where secondary data is used, the notified body shall check whether the correct data sets, prescribed by applicable product-specific calculation rules contained in the applicable harmonised technical specification or methodology provided by the Commission, are used. Where company specific data is used, the reliability of that data needs to be verified. To that end, the notified body shall undertake an audit of the manufacturing plant to which they refer and shall examine all data relating to suppliers and service providers. Notified bodies may extend their audit to suppliers and service providers who are obliged to cooperate in accordance with Article 30.

- 5. System 3 Notified body focusing on the product type determination
 - (a) The manufacturer shall carry out:
 - (i) an assessment of the performance of the product on the basis of testing (including sampling of the item(s) to be taken as representative of the type), type calculation, tabulated values or descriptive documentation of that product;
 - (ii) factory production control;
 - (iii) verification whether the <u>drawing up of</u> technical documentation containings full proof of the correct application of this Regulation with regard to the assessment of performance;
 - (iv) verification whether the <u>drawing up of</u> technical documentation contain<u>ings full</u> proof of conformity with <u>the applicable</u> product requirements <u>of under</u> this Regulation.
 - (b) The notified body shall issue the certificate of performance and of conformity on the basis of:
 - (i) confirmation of the correct determination of the product type and of the product category;
 - (i.a) and confirmation of the correct an assessment of the performance of the product on the basis of type testing (based on sampling carried out by the manufacturer), type calculation or tabulated values and, in all these cases, review of the documentation of the product;
 - (ii) undertaking a check of 20 random points falling under the paragraphs (a) (iii) and (iv) and refuse the issuing of a certificate in case it detects more than 2 non-compliance or one particularly grave non-compliance, amongst these 20 points and the other verifications to be made in accordance with this paragraph.

- 6. System 4 Manufacturer's self-verification and self-certification
 - (a) The manufacturer shall carry out:
 - (i) an assessment of the performance of the product on the basis of testing (including sampling of the item(s) to be taken as representative of the type), type calculation, tabulated values or descriptive documentation of that product;
 - (ii) confirmation of the correct determination of the product type and of the product category on the basis of type testing, type calculation or tabulated values and, in all these cases, review of the documentation of the product;
 - (iii) factory production control;
 - (iv) verification whether the <u>drawing up of</u> technical documentation containings full proof of the correct application of this Regulation with regard to the assessment of performance;
 - (v) verification whether the drawing up of technical documentation containings full proof of conformity with the applicable product requirements of under this Regulation.
 - (b) There is no task for the notified body.

- 7. <u>Horizontal rules pertaining to some</u> For all <u>of</u> the systems above the following shall apply:
 - (a) When a system includes an iInspection of the manufacturing plant by a notified body, those inspections shall be carried out as on-site audits, cover the entire technical part of the plant all locations at which significant manufacturing processes take place and, at least, verify with regard to the following elements, which shall ensure a continuous orderly manufacturing process: [1+, 1 and 2+]
 - (i) appropriate competence of the personnel;
 - (ii) appropriateness of the technical equipment;
 - (iii) appropriateness of the facilities and other conditions influencing the manufacturing;
 - (iv) outline of the intended factory production control.
 - (b) When a system includes fFactory production control, those controls shall cover the production process from receipt of the raw materials and components to the dispatch of the product once the production has started ('gate to gate' approach) once that production has started, and at least include the following elements:. It shall assess whether this process is designed and optimised in view of the goal [1+, 1, 2+, 3+, 3 and 4]
 - (i) ensuring that the products conform with the product type and therefore reach the performances declared in the declaration of performance and conformity and are compliant with the requirements set out in or under this Regulation;
 - (ii) application of the technical details necessary for the implementation of the

 assessment and verification system or systems as defined in harmonised technical

 specifications, European assessment documents and harmonised standards, including
 the relevant factory production control checks.

- (c) When a system includes <u>f</u>Further testing of samples, <u>those</u> the following applies: [1+ and 1]
 - (i) tests shall include constitute of testing of an adequate number of products, as defined in harmonised technical specifications, European assessment documents and harmonised standards, with regard to conformity with the product type, with zero tolerance for non-conformity, unless another tolerance is defined in the harmonised technical specifications;
 - (ii) in case tests are not suitable for the product, the product type may be defined using the applicable extended application rules referred in harmonised technical specifications, European assessment documents and harmonised standards, where available. Notified bodies confirming the correct determination of the product type shall also confirm the correct application of the relevant extended application rules;
 - (iii) results from tests undertaken by another manufacturer or notified body may be used in accordance with Article 67.
- (d) When a system includes the vVerification of sampled items, sampling for such verifications shall, to 50 %, target items which are most likely to contain deficiencies and, to another 50 %, target items chosen at random.
- (e) Verification of environmental sustainability shall constitute of the verification of all calculations and verification of 10 samples of company-specific or secondary data factored in, with zero tolerance for incorrectness. In that context, the notified body shall verify whether the applicable rules on modelling and calculation laid down in the applicable harmonised technical specification or methodology provided by the Commission are followed.

In case an IT tool provided by the Commission is used, the verification focuses on the correct use of the tool. Where secondary data is used, the notified body shall check whether the correct data sets, prescribed by applicable product-specific calculation rules contained in the applicable harmonised technical specification or methodology provided by the Commission, are used. Where company-specific data is used, the reliability of that data needs to be verified. To that end, the notified body shall undertake an audit of the manufacturing plant to which they refer and shall examine all data relating to suppliers and service providers. Notified bodies may extend their audit to suppliers and service providers who are obliged to cooperate in accordance with Article 30.

- (f) When a system sets a maximum limit for non-compliances and that limit has Where the above mentioned failure rates have been trespassed or where a grave error or the intention to cheat has been detected, the notified body shall refuse issuing a certificate for at least one year or withdraw the certificate whilst permitting issuing a new one only after one year.
- (g) Notified bodies that are undertaking tasks under Systems 1+, 1, and 3 as well as manufacturers that are undertaking tasks under Systems 2+ and 4 shall consider the When a European Technical Assessment is issued for the a product in question as the assessment of the performance of that product. Nnotified bodies and manufacturers shall therefore undertake the assessment of the performance of that product tasks referred to in points 1.(b)(ii), 2.(b)(ii), 3.(a)(i), 5.(a)(i) and 6(a)(i), respectively, only where there is evidence that these it hasve not or not appropriately been executed by the TAB. [all systems]

ANNEX Va

List of the legal acts referred to in Article 8

- 1. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers
- [2. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC]
- 3. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18

 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
- <u>Directive 2008/98/EC of the European Parliament and of the Council of 19 November</u>
 <u>2008 on waste and repealing certain Directives</u>
- 5. Regulation (EC) No 1272/ of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
- 6. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

- 7. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom
- 8. Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels
- 9. Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility
- 10. Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments
- 11. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits
- 12. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC
- 13. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment

- 14. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC
- 15. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC
- Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016on the interoperability of the rail system within the European Union
- 17. Regulation (EU) 2023/[XX] of the European Parliament and of the Council of [Day Month] 2023 on Machinery
- 18. Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing

 Directive 2009/125/EC [COM(2022) 142]
- 19. Proposal for a Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020 [COM(2022) 454]
- 20. Proposal for a Directive of the European Parliament and of the Council on adapting noncontractual civil liability rules to artificial intelligence [COM(2022) 496]
- 21. Proposal for a Regulation of the European Parliament and of the Council establishing a

 Union certification framework for carbon removals [COM(2022) 672]
- 22. Proposal for a Regulation of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) 168/2013, (EU) 2018/858, 2018/1724 and (EU) 2019/1020 [COM(2023) 160]
- 23. Proposal for a Directive of the European Parliament and of the Council on substantiation and communication of explicit environmental claims [COM(2023) 166]

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