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**NOTE**

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Subject:	Proposal for a Regulation of the European Parliament and of the Council laying down harmonised conditions for the marketing of construction products, amending Regulation (EU) 2019/1020 and repealing Regulation (EU) 305/2011 - Partial Presidency Compromise Text

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 14 February 2023.

**Proposal for a Regulation of the European Parliament and of the Council laying down harmonised conditions for the marketing of construction products, amending Regulation (EU) 2019/1020 and repealing Regulation (EU) 305/2011**

Partial Presidency Compromise Text

*Article 7*

**Harmonised zone and national measures**

1. This Regulation, including the harmonised technical specifications and Commission acts of general applicability adopted in accordance with it, establishes a harmonised zone. The harmonised zone shall be presumed to be comprehensive, covering all ~~potential-existing or future~~ essential characteristics and product requirements ~~for products~~ other than those covered by other Union law.
2. Member States shall respect the harmonised zone in their national law, other rules or administrative action and shall not set additional requirements for or prohibit or impede the making available of products covered by it, unless it is specified in the respective harmonised technical specification that the respective requirements constitute only minimum requirements. Member States shall not prohibit or impede the use of products in compliance with this regulation when the declared performances correspond to the requirements for such use in that Member State.

Member States shall ensure that products 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~~ Member states shall in particular apply the following:

- (a) no information, 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;

- (c) unless ~~otherwise~~ specified in applicable harmonised technical specifications ~~accordance with Article 5(31)~~, national law, other rules or administrative action 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 introduced other than the CE marking, and any existing references to such markings in national measures shall be withdrawn;
- (e) national law, other rules or administrative action shall replicate and not request more or less than what has been required by threshold levels established in accordance with Article ~~4a(4)~~;
- (f) national law, other rules or administrative 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)~~, 4a or ~~in Article 5(2)~~, national law, other rules or administrative action shall, both for construction works and in relation to the characteristics of or requirements for products, not refer to other assessment methods 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 sub-classes 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. ~~In line with Regulation (EU) 1025/2012, Commission shall inform the Member States about its intention to draw up a new standardisation request.~~ 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 covered by harmonised technical specifications to the extent that their development is technically and economically proportionate possible. [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 in derogation of paragraphs 2 and 2a, 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, where applicable.

5. The Commission shall, by means of implementing acts, authorise the national measure notified under paragraph 4 where:

- (a) it ascertains that the regulation or administrative measure appears duly justified in the light of imperative grounds of health, safety or protection of the environment 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;
- (e) the notified regulation or administrative measure does not constitute a disproportionately large obstacle to the functioning of the Union market; and
- (f) 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 Member States to introduce mandatory deposit-refund systems, 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. Member States may ban the destruction of products taken back in accordance with Article 22(2), point (j) and Article 26 or make the destruction of these products dependent on their prior making available on a national brokering platform for non-commercial use of products.

#### *Article 9*

##### ***Declaration of performance and conformity***

1. Where a product is covered by a harmonised technical specification adopted in accordance with Articles ~~4(2)~~ or ~~4a(3)~~, the manufacturer shall undergo the applicable assessment and verification system set out in Annex V and draw up a declaration of performance and conformity before such a product is placed on the market. Where a product is covered by a harmonised technical specification adopted in accordance with Article 5, the manufacturer shall also verify the product's compliance with applicable product requirements that have been specified by delegated acts.

A manufacturer of a product which is not covered by any harmonised technical specification may issue a declaration of performance and conformity in accordance with the relevant European assessment document and European technical assessment.

2. Where a product is covered by a harmonised technical specification, information about its performance in relation to the essential characteristics laid down in the applicable harmonised technical specification may be provided elsewhere than in the declaration of performance and conformity only if in parallel provided in the declaration of performance and conformity. This obligation shall not apply to situations where, in accordance with Article 10, no declaration of performance and conformity has been drawn up.
3. By drawing up the declaration of performance and conformity, the manufacturer assumes responsibility for the conformity of the product with ~~such its~~ declared performance and any applicable product requirements ~~and becomes liable in accordance with Union and national laws on contractual and extra-contractual liability, and this even where it did not act negligently~~. In the absence of objective indications to the contrary, Member States shall presume the declaration of performance and conformity drawn up by the manufacturer to be accurate and reliable.

In case of non-compliance or absence of a declaration of performance and conformity when such a declaration is mandated, the product may not be made available on the market.

#### *Article 11*

##### *Content of the declaration of performance and conformity*

1. The declaration of performance and conformity shall express the performance of products in relation to the essential characteristics of those products in accordance with the relevant harmonised technical specifications or European assessment document.

Where product requirements specified in accordance with Article 5 are applicable, the declaration of performance and conformity shall state that the fulfilment of those requirements has been demonstrated.

1. The declaration of performance and conformity shall be drawn up using the model set out in Annex II ~~without the section relating to conformity~~. The declaration of performance and conformity shall at least cover the performance with regard to the ~~mandatory~~ essential characteristics of climate change effects listed as mandatory in Annex I-A ~~Part A~~ Point 2, as well as those essential characteristics mandatory by virtue of harmonised technical specifications ~~or delegated acts~~ adopted in accordance with Article 4a (3), ~~and the assessment of environmental sustainability referred to in Article 22(1)~~.
- 2a. The declaration of performance and conformity shall include an assessment of the product's environmental sustainability in respect of the predetermined environmental characteristics listed in Annex I-A Point 2, when those characteristics are either mandatory or rendered applicable in accordance with relevant harmonised technical specifications. The data from this assessment shall be produced using, once available, the latest version of the software made freely available on the website of the European Commission.
- 2b. No other marking than the CE marking may be placed on the declaration of performance and conformity.
3. The Commission is empowered to amend the model set out in Annex II by delegated acts adopted in accordance with Article 87 to ~~permit the inclusion of further information in order to allow economic operators to cover~~ adapt it to technical progress as regards new information needs, data structures and exchange formats, and to ensure interoperability with the database or system according to Article 78 and, if relevant, with other databases or systems.



4. The information referred to in Articles 31 or ~~as the case may be, in Article~~ 33 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>1</sup> shall be provided together with the declaration of performance and conformity.

*Article 13*

***Declaration of conformity***

- ~~1. Before placing a product on the market, the manufacturer who is not exempted from the obligation to produce a declaration of performance shall:~~
- ~~(a) verify the product's compliance with the product requirements of Annex I Part B and C to the extent that they have been specified by delegated acts in accordance with Article 5(2), and with the product requirements of Annex I Part D;~~
  - ~~(b) undergo the respective assessment and verification system set out in Annex V; and~~
  - ~~(c) draw up a declaration of conformity.~~
- ~~2. The manufacturer may decide to issue a declaration of conformity in accordance with paragraph 1 even where exempted from the obligation to produce a declaration of performance.~~
- ~~3. By the declaration of conformity, the manufacturer assumes responsibility for the conformity of the product with the product requirements and becomes liable in accordance with national laws on contractual and extra-contractual liability, and this even where it did not act negligently. In case of non-compliance or absence of a declaration of conformity, the product may not be made available on the market. In the absence of objective indications to the contrary, Member States shall presume the declaration of conformity drawn up by the manufacturer to be accurate and reliable.~~
- [Article merged with Article 9]

<sup>1</sup> 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 (OJ L 396, 30.12.2006, p. 1.).

## *Article 14*

### ***Content of the declaration of conformity***

- ~~1. The declaration of conformity shall express conformity of a product with product requirements referred to in Article 5(1) and (2).~~
- ~~2. The manufacturer shall combine the declaration of conformity with the declaration of performance into a single declaration, to be labelled “Declaration of performance and conformity” as set out in Annex II.~~
- ~~3. Article 11(2) to (4) and Article 12 shall apply with regard to the declaration of conformity.~~
- ~~4. The manufacturer shall fulfil the obligations of this Article as from the first revision of the declaration of performance undertaken by the manufacturer after the date of application of harmonised technical specification, for the respective product family or category, but at the latest 3 years after that date. [Article merged with Article 11]~~

## *Article 16*

### ***General principles and use of CE marking***

1. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
2. The CE marking shall only be affixed to those products for which the manufacturer has drawn up a declaration of performance ~~or~~ and conformity in accordance with Articles 9 and 11 ~~to 14. The CE marking shall be affixed to key parts.~~ The CE marking may not be affixed to parts or materials intended to be used for products covered by this Regulation for which the manufacturer has opted for the application of this Regulation in accordance with article 2(1)(e) which are not key parts.
- ~~3. If neither a declaration of performance nor a declaration of conformity has been drawn up by the manufacturer, the CE marking shall not be affixed.~~

4. By affixing or having affixed the CE marking, the economic operator indicates that it ~~takes~~ has assumed responsibility for the conformity of the product with the declared performance and applicable product requirements ~~of this Regulation or~~ laid down in accordance with this Regulation. ~~By affixing the CE marking, the economic operator becomes liable for the declared performance and the fulfilment of these requirements in accordance with national law on contractual and extra-contractual liability.~~
5. The CE marking shall be the only marking which attests the performance of the product with regard to assessed essential characteristics and the conformity of the product with this Regulation.

~~Member States shall not introduce any references or shall withdraw any references in national measures to a marking attesting conformity with requirements or the declared performance in relation to the essential characteristics covered by the harmonised zone.~~  
[Moved to Article 7(2a)(d1)]

- 5a. No other marking than marking set out by Union legislation may be affixed on a product in a distance smaller than the double length of the marking “CE” measured from any point of the CE and the other marking set out by Union law.

- ~~6. — A Member State shall not prohibit or impede, within its territory or under its responsibility, the making available on the market or the use of products bearing the CE marking, when the declared performances correspond to the requirements for such use in that Member State.~~

~~A Member State shall not prohibit or impede, within its territory or under its responsibility, the making available on the market or the use of products bearing the CE marking, when the product conforms with product requirements set up in or by means of this Regulation, unless it is specified in the respective harmonised technical specification that the respective requirements constitute only minimum requirements.~~ [Moved to Article 7(2)]

- ~~7. — A Member State shall ensure that the use of products bearing the CE marking 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.~~ [Moved to Article 7(2)]

***Rules and conditions for the affixing of CE marking***

1. The CE marking shall be affixed visibly, legibly and indelibly to the product or to a label attached to it. Where this is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging or to the accompanying documents.
2. The CE marking shall be followed by:
  - (a) the two last digits of the year in which it was first affixed;
  - (b) the name and the registered address of the manufacturer, or the identifying mark allowing identification of the name and address of the manufacturer easily and without any ambiguity;
  - (c) the name and the registered address of the authorised representative, or the identifying mark allowing identification of the name and address of the authorised representative easily and without any ambiguity where the manufacturer does not have a place of business in the Union or where the manufacturer chooses to have an authorised representative;
  - (d) the unique identification code of the product-type, ~~the permalink to the manufacturer's products registration(s) in Union databases and the precise location therein where the product can be found;~~
  - ~~(e) the permalink to the manufacturer's own product presentation website, if any there is any;~~
  - (f) the reference number of the declaration of performance and conformity; and
  - (g) the identification number of the notified body, if applicable.

The items listed in points d) to f) may be replaced by a permalink to the combined declaration of performance and of conformity (electronic CE marking).
3. The CE marking shall be affixed before the product is placed on the market ~~or directly installed into a construction work~~. It may be subsequently followed by a pictogram or any other mark indicating a special risk or use.

## Article 18

### Other markings

~~Affixing~~ Markings other than the CE marking, including private ones ~~that may not be affixed on a product only if they do not indicate that the product's performance in relation to essential characteristics covered by applicable or refer to~~ harmonised technical specifications ~~had to be assessed in a different way than what has been laid down by this Regulation. Such markings may however be permitted in accordance with Annex I-D point 4, or to product requirements or essential characteristics or assessment methods included in the harmonised zone, is forbidden. This interdiction shall apply to the physical label marking as well as any other reference to such marking in advertising or other public materials.~~

~~No other marking than marking set out by Union legislation may be affixed on a product in a distance smaller than the double length of the CE marking measured from any point of the marking "CE" and the other marking set out by Union law. [Moved to article 16(5a)]~~

~~No other marking than the CE marking may be placed on the declaration of performance or the declaration of conformity. [Moved to article 11(2b)]~~

## Article 21

### Obligations of manufacturers

[...]

- ~~2.~~ The manufacturer shall, ~~unless permitted for in accordance with Annex I-D point 4,~~ refrain from any claim about ~~the~~ a product's performance in relation to essential characteristics covered by harmonised technical specifications applicable to that of a product ~~that when such a claim~~ is not based on:

- ~~(a)~~ the assessment methods contained in ~~a~~ those harmonised technical specifications ~~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.~~

[...]

## **ANNEX I~~PART D~~: Product information requirements**

[...]

3. Harmonised technical specifications may permit manufacturers to even though otherwise not allowed for under this Regulation, provide certain information items or state certain claims relevant for Member States, users or occupants, under the condition that:
    - (a) the respective Member States' regulation is compatible with Union law,
    - (b) it is made clear that the respective information items permitted by the harmonised technical specifications do not relate to Union law and are not mandatory.
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## ANNEX II

### Declaration of Performance and ~~of~~ Conformity<sup>1</sup>

Name of the Manufacturer

Declaration No ...<sup>2</sup>

Version No ...<sup>3</sup>

Date of that version ...

1. Product description

- (a) unique identification code of the product type, and the ranges of batch numbers and serial numbers covered if already determined for the respective product type;
- (b) product category as defined by harmonised technical specifications or European Assessment Documents;
- (c) intended uses of the product, within the scope of ~~necessarily falling under those intended uses for which~~ the applicable harmonised technical specification or European Assessment Document ~~has been developed~~, with facultative additional information on the intended users, or the conditions for safe and good use;
- (d) dimensions or grading of the product, where applicable;
- (e) main materials or substances used, where applicable;
- (f) information to be provided in accordance with Regulation (EC) 1907/2006;
- (g) key parts of the product, including traceability information on the key part if it has previously been placed separately on the market;

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<sup>1</sup> When ~~re~~ a Declaration of Performance and Conformity is issued in relation to a product not subject to product requirements specified in accordance with Article 5(1) without parallel issuing of a Declaration of Conformity, the points 12., 12a. and 13c. ~~shall~~ may be omitted.

<sup>2</sup> Only one unique, unequivocal declaration number per product type shall be used, even where there are variants, variants being variations of the product type that do not influence performance or conformity of the product.

<sup>3</sup> Different versions may be issued, e.g. to correct mistakes or add complementary information.

- (h) estimated average and minimum service life time for the intended use foreseen for the product (durability);
- (i) variants, if any, and their descriptions;
- (j) information required by harmonised technical specifications adopted in accordance with Article 5 and falling under Annex I-D Part D, where applicable.
2. Permalinks as regards the following:
- (a) the manufacturer's products registration(s) in EU databases, and the precise location therein where the product can be found, ~~and to his own product presentation website;~~
- ~~(b) any voluntarily or mandatorily used products registration database or website, and the precise location therein where the product can be found;~~
- (c) instructions for use, if specified in accordance with Annex I-D ~~Part D~~ point 1.3.
3. Manufacturer:
- (a) name;
- (b) registered trade name or registered trade mark;
- (c) registered place of business;
- (d) postal address;
- (e) telephone;
- (f) email address;
- (g) website, where available;
- ~~(h) social media contact details;~~
- ~~(i) where available, specific contact details for providing information on installation, maintenance, use, de-construction, and on the handling of risks or product failure.~~





4. Authorised representative:

- (a) name;
- (b) registered trade name or registered trade mark;
- (c) registered place of business;
- (d) postal address;
- (e) telephone;
- (f) email address;
- (g) website, where available;
- ~~(h) —social media contact details;~~
- ~~(i) —where available, specific contact details for information on installation, maintenance, use, de-construction, on the handling of risks and on actions in case of product failure.~~

5. Notified body or bodies, where applicable:

- (a) name;
- ~~(a1) identification number;~~
- (b) registered trade name, where available;
- (c) registered place of business;
- (d) postal address;
- (e) telephone;
- (f) email address;
- (g) website, where available;
- ~~(h) —social media contact details.~~

6. Technical Assessment Body, where applicable:

- (a) name;
- (b) registered trade name, where available;
- (c) registered place of business;
- (d) postal address;
- (e) telephone;
- (f) email address;
- (g) website, where available;
- ~~(h) —social media contact details.~~

7. Assessment and verification system(s) applied and reference to certificate(s) or report(s) issued
8. Harmonised technical specifications laying down essential characteristics applied:  
(reference number and date of issue)
9. European Assessment Document applied:  
(reference number and date of issue)
10. European Technical Assessment issued:  
(technical assessment body, reference number and date of issue)
11. Declared performances and sustainability characteristics:
- (a) the list of essential characteristics, as determined in the harmonised technical specification or European Assessment Document for the respective product category for which a performance is declared.
  - (b) the performance of the product, by calculated values, levels or classes, or in a description. Respective values, levels or classes shall be reproduced in the declaration of performance itself and thus cannot be expressed solely by inserting references to other documents. However, the performance of structural behaviour of a product may be expressed by referring to attached production documentation or structural design calculations.
  - (c) the environmental sustainability data calculated in accordance with Article 11(2a) 22(1), in particular where they fit under the essential characteristics listed in Annex I Part A, point 2, in case the respective rules covering the product category have become applicable at the time of placing on the market or direct installation.
12. ~~The product identified above is in conformity with the following~~ Applicable product requirements of Annex I Part B and C as specified by the following harmonised technical specifications adopted in accordance with Article 5 <sup>†</sup>:  
(reference number and date of issue)

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<sup>†</sup> ~~Cite the respective harmonised technical specifications.~~

12a. References to the harmonised standards referred to in Article 5(2b) that have been applied, including the date of the standard, or references to the other technical specifications, including their date, in relation to which conformity is declared. In the event of partial application of harmonised standards, the declaration shall specify the parts which have been applied.

13. Declarations:

- (a) the performance of the product identified above is in conformity with the set of declared performances under point 11;
- (b) the sustainability data of the product identified above have been correctly calculated on the basis of the product category rules applicable to it;
- (c) the product identified above is in conformity with the requirements listed under point 12.

Signed for and on behalf of the manufacturer by:

[name, function<sup>1</sup>]

At [place]

on [date of issue]

[signature]

\_\_\_\_\_

<sup>1</sup> The person signing shall be empowered by virtue of national law to represent the manufacturer, be it on the basis of a mandate, be it due to her/his role as legal representative.

**ANNEX V**  
**Assessment and verification systems (AVS)**

The manufacturer shall in accordance with Article 21(1), be responsible for correctly determin~~e~~ing 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 verif~~y~~ing these determinations, including the verification that no identical 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 technical documentation contains ~~full~~ proof of the correct application of this Regulation with regard to the assessment of performance;
    - (iv) verification whether the technical documentation contains ~~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;

- (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 technical documentation contains ~~full~~ proof of the correct application of this Regulation with regard to the assessment of performance;
- (iv) verification whether the technical documentation contains ~~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;
- (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 technical documentation contains ~~full~~ proof of the correct application of this Regulation with regard to the assessment of performance;
  - (v) verification whether the technical documentation contains ~~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;
  - (iii) ~~full~~ verification of the tasks under paragraphs (a) (iv) and (v).

- (c) 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 the assessment of the performance of the product in relation to essential characteristics or product requirements ~~related to environmental sustainability~~ and keep it updated.
- (b) The notified body shall in a validation report, in particular in view of input values, assumptions made and compliance with applicable generic or product category specific rules:
  - (i) verify the manufacturer’s initial and updated assessment;
  - (ii) validate the process applied to generate that assessment.

- (c) Validation shall include 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.

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 technical documentation contains ~~full~~ proof of the correct application of this Regulation with regard to the assessment of performance;
  - (iv) verification whether the technical documentation contains ~~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:
- (i) confirmation of the correct determination of the product type and of the product category;
  - (ia) ~~and~~ confirmation of the correct 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 technical documentation contains ~~full~~ proof of the correct application of this Regulation with regard to the assessment of performance;
  - (v) verification whether the technical documentation contains ~~full~~ proof of conformity with the applicable product requirements ~~of under~~ this Regulation.
- (b) There is no task for the notified body.

7. Horizontal rules pertaining to some For all of the systems above ~~the following shall apply~~:

- (a) When a system includes an inspection of the manufacturing plant by a notified body, those inspections shall cover the entire technical part of the plant, at least 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;
- (b) When a system includes factory production control, those controls shall cover the process from receipt of the raw materials and components to the dispatch of the product once the production has started ('gate to gate' approach). It shall assess whether this process is designed and optimised in view of the goal that the products conform with the product type and therefore reach the performances declared in the declaration of performance and are compliant with the requirements set out in or under this Regulation. [1+, 1, 2+, 3 and 4]
- (c) When a system includes further testing of samples, those tests shall include constitute of testing of an adequate number of products, as defined in harmonised technical specifications, with regard to conformity with the product type, with zero tolerance for non-conformity, unless another tolerance is defined in the harmonised technical specifications. [1+ and 1]
- (d) When a system includes the verification 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. [all systems]

- (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. [Moved to point 4 letter (c)]~~

- (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. [1+, 1, 2+ and 3]
- (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. N~~otified 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~~ has ~~ve~~ not or not appropriately been executed by the TAB. [all systems]