Council of the European Union

Brussels, 26 May 2025
(OR. en)

9318/25
ADD 1

Interinstitutional File:
2025/0134 (COD)

SIMPL 33	TELECOM 158
ANTICI 38	POLCOM 106
EF 165	COMPET 417
ECOFIN 591	ENV 393
MI 331	CLIMA 166
ECO 16	TRANS 201
ENT 80	ENER 158
IA 55	CODEC 673
IND 158	

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	21 May 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2025) 504 annex
Subject:	ANNEXES to the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 76512008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 202311542 and (EU) 2024/1781 as regards digitalisation and common specifications.

Delegations will find attached document COM(2025) 504 annexes.

Encl.: COM(2025) 504 annex

EUROPEAN
COMMISSION

Brussels, 21.5.2025
COM(2025) 504 final

ANNEXES 1 to 5

ANNEXES

to the

Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications

{SWD(2025) 130 final}

ANNEX I

Annexes III to IX to Regulation (EU) 2016/424 are amended as follows:

(1) Annex III is amended as follows:

(a) in point 3, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 4, points 4.2 and 4.3 are replaced by the following:

‘4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;’;

(c) in point 6, first subparagraph, the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, any conditions for its validity, the necessary data for identification of the approved type (subsystem or safety component) and if relevant, descriptions of its functioning.’;

(2) Annex IV is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 3.3., first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(3) Annex V is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) point 4.1 is replaced by the following:

‘4.1. All subsystems or safety components shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Regulation.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(c) point 5.2. is replaced by the following:

'5.2. A random sample shall be taken from each lot. All the subsystems or safety components in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(4) Annex VI is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3.2., paragraph 1 is replaced by the following:

'The notified body shall examine the technical documentation for the subsystem or the safety component and shall carry out the appropriate examinations and tests set out in the relevant harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the subsystem or the safety component with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.';

(5) Annex VII is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3.2., point (b) is replaced by the following:

'(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means, including other relevant technical specifications, that will be used to ensure that the essential requirements of this Regulation will be met;';

(c) in point 3.3., first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.';

(d) in point 3.6.2., point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer;';

(e) in point 3.6.3, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’;

(6) in Annex VIII, point 2, point (c) is replaced by the following:

‘(c) a list of the harmonised standards referred to in Article 17, applied in full or in part, the references of which have been published in the Official Journal of the European Union, or a list of common specifications, applied in full or in part, and where those harmonised standards or common specifications, have not been applied descriptions of the solutions adopted to meet the essential requirements of this Regulation including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(7) Annex IX is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’.

ANNEX II

Annexes II, III, V, VII, VIII, and IX to Regulation (EU) 2016/425 are amended as follows:

(1) in Annex II, point 1.4 is amended as follows:

(a) in the first subparagraph, the first sentence is replaced by the following:

'In addition to the name, postal address and digital contact of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:';

(b) points (k) and (l) are replaced by the following:

'(k) references to the relevant harmonised standard(s) or common specification (s) used, including the date of the standard(s) or specification(s), or references to the other technical specifications used;

(l) the internet address or machine-readable code through which the EU declaration of conformity can be accessed.';

(2) in Annex III, points (f) and (g) are replaced by the following:

'(f) the references of the harmonised standards referred to in Article 14 or the common specifications referred to in Article 14a that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts which have been applied;

(g) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;';

(3) Annex V is amended as follows:

(a) in point 3., point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 4, points (d) to (f) are replaced by the following:

'(d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications as well as the elements which have been designed in accordance with other technical specifications;

(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

(f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.';

(c) point 6.2., is amended as follows:

(i) point (b) is replaced by the following:

'(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, the latter's name, postal address and digital contact;';

(ii) point (e) is replaced by the following:

‘(e) where harmonised standards or common specifications have been fully or partially applied, the references of those standards or specifications or parts thereof;’;

(d) point 7.6. is amended as follows:

(i) point (a) is replaced by the following:

‘(a) his name, postal address and digital contact and data identifying the EU type-examination certificate concerned;’;

(ii) point (b) is replaced by the following:

‘(b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or common specifications or other technical specifications applied;’;

(4) Annex VII is amended as follows:

(a) in point 3., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact;’;

(b) point 4.3. is replaced by the following:

‘4.3. An adequate statistical sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined, and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.’;

(5) Annex VIII is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(6) Annex IX is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:’.

ANNEX III

Annexes III and V to Regulation (EU) 2016/426 are amended as follows:

(1) Annex III is amended as follows:

(a) point 1.3.1. is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point (c), point (4) is replaced by the following:

‘(4) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iii) in point (e), the second sentence is replaced by the following:

‘(e) This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(b) in point 1.4., points 1.4.3. and 1.4.4. are replaced by the following:

‘1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Regulation;’;

(c) in point 1.6., first subparagraph, the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity, the necessary data for identification of the approved type, such as the type of gas, appliance category and gas supply pressure, and, if relevant, descriptions of its functioning.’;

(d) In point 2.3, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final appliances or fittings taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to check the conformity of the appliance or the fitting with the relevant requirements of this Regulation.’;

(e) in point 3.3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(f) in point 3.3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(g) in point 4.3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(h) in point 4.3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(i) point 5.4.1. is replaced by the following:

‘5.4.1. All appliances or fittings shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specifications, and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify conformity with the approved type described in the EU type-examination certificate and with the appropriate requirements of this Regulation.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(j) point 5.5.2. is replaced by the following:

‘5.5.2. A random sample shall be taken from each lot in accordance with the requirements of point 5.5.3. All appliances or fittings in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(k) in point 6.2.1., point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.’;

(l) in point 6.4., the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards or common specifications and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the appliances or fittings with the applicable requirements of this Regulation, or have them

carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.';

(2) Annex V is amended as follows:

(a) point 2 is replaced by the following:

'2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:';

(b) paragraph 6 is replaced by the following:

'6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared'.

ANNEX IV

Annexes III, V, VII, IX, and X to Regulation (EU) 2023/1230 are amended as follows:

(1) Annex III is amended as follows:

(a) in point 1.7.4.2., point 1 is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the business name, full postal address and digital contact of the manufacturer and, where applicable, of its authorised representative;’;

(ii) point (c) is replaced by the following:

‘(c) the EU declaration of conformity, or the internet address or machine readable code, through which the EU declaration of conformity can be accessed, in accordance with Article 10(8);’;

(b) point 4.3.1. is amended as follows:

(i) the first subparagraph is replaced by the following:

‘Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name, postal address and digital contact of the manufacturer and the identifying reference of the relevant certificate.’;

(ii) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;’;

(2) Annex V is amended as follows:

(a) in Part A, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.’;

(b) in Part B, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.’;

(3) Annex VII is amended as follows:

(a) in point 3., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’;

(b) in point 6.2., point (b) is replaced by the following:

‘(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’;

(c) in point 7.6., point (a) is replaced by the following:

‘(a) its name, postal address and digital contact and data identifying the EU type-examination certificate concerned;’;

(4) in Annex IX, point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’;

(5) Annex X is amended as follows:

(a) in point 2., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’.

ANNEX V

Annexes VIII, IX and XIII to Regulation (EU) 2023/1542 are amended as follows:

(1) in Annex VIII, Module D1: Quality assurance of the production process, point 5.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the manufacturer’s authorised representative, its name, postal address and digital contact as well,’;

(2) in Annex IX, point 2 is replaced by the following:

‘Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative:’;

(3) in Annex XIII, point 1, the following point (t) is added:

‘(t) ‘clear, understandable and readable instructions for use in a format that makes it possible to print, download and save them on an electronic device so that the user can access them at all times, in particular during a breakdown of the battery (only for stationary battery energy storage systems).’