

Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products (Text with EEA relevance)

CHAPTER II

TECHNICAL SPECIFICATIONS RELATED TO THE UNIQUE IDENTIFIER

SECTION 1

Common provisions

Article 3

ID issuer

- 1 Each Member State shall appoint an entity (the ‘ID issuer’) responsible for generating and issuing unique identifiers, in accordance with Articles 8, 9, 11 and 13, within a maximum period of one year from the date of entry into force of this Implementing Regulation.
- 2 Member States shall ensure that an ID issuer that intends to have recourse to subcontractors for the performance of its functions shall only be considered for appointment if the identity of any subcontractors proposed has been communicated to them.
- 3 The ID issuer shall be independent and comply with the criteria set out in Article 35.
- 4 Each ID issuer shall be equipped with a unique identification code. The code shall be composed of alphanumeric characters and comply with the International Organization for Standardisation/International Electrotechnical Commission standard (‘ISO/IEC’) 15459-2:2015.
- 5 Where the same ID issuer is appointed in more than one Member State, it shall be identifiable by the same code.
- 6 Member States shall notify the Commission of the appointment of the ID issuer and of its identification code within one month of its appointment.
- 7 Member States shall ensure that information related to the identity of the ID issuer appointed and its identification code is made publicly available and accessible online.
- 8 Each Member State shall put in place adequate measures to ensure:
 - a that the ID issuer it has appointed continues to comply with the requirement of independence in accordance with Article 35; and
 - b the continuous operation of the services provided by successive ID issuers, in case a new ID issuer is appointed to take over the services from the previous ID issuer. For this purpose Member States shall require the ID issuer to develop an exit plan laying down the procedure to be followed to guarantee the continuity of the operations until the new ID issuer is appointed.
- 9 The ID issuer may establish and charge fees to economic operators solely for generating and issuing unique identifiers. Fees are to be non-discriminatory and proportionate to

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the number of unique identifiers generated and issued to economic operators taking into account the mode of delivery.

Article 4

Competent ID issuers for generating and issuing unique identifiers

1 For tobacco products manufactured in the Union, the competent ID issuer shall be the entity appointed for the Member State in which the products are manufactured.

By derogation to the first subparagraph, the competent ID issuer shall be the entity appointed for the Member State on whose market the products are placed, where such a requirement is imposed by that Member State.

2 For tobacco products imported into the Union, the competent ID issuer shall be the entity appointed for the Member State on whose market the products are placed.

3 For tobacco products aggregated in the Union, the competent ID issuer shall be the entity appointed for the Member State in which the products are aggregated.

4 For tobacco products destined for export, the competent ID issuer shall be the entity appointed for the Member State in which the products are manufactured.

5 In the event of the temporary absence of the competent ID issuer, the Commission may authorise economic operators to use the services of another ID issuer that has been appointed in accordance with Article 3.

Article 5

Validity of unique identifiers and deactivation

1 Unique identifiers generated by ID issuers may be used to mark unit packets or aggregated packaging, as provided for by Articles 6 and 10, within a maximum period of six months from the date of receipt of the unique identifiers by the economic operator. After this time period unique identifiers shall become invalid and economic operators shall ensure that they are not used to mark unit packets or aggregated packaging.

2 The repositories system shall ensure that the unique identifiers that have not been used within the six months period referred to in paragraph 1 shall be automatically deactivated.

3 At any time, manufacturers and importers may obtain the deactivation of unique identifiers by transmitting a deactivation request to the relevant primary repository. Other economic operators may obtain the deactivation of the unique identifiers by transmitting a deactivation request via the router. The deactivation request shall be introduced electronically, in accordance with Article 36, and shall contain the information listed in point 2.3 of Section 2 of Chapter II of Annex II, in the format indicated therein. The deactivation shall not interfere with the integrity of the information already stored related to the unique identifier.

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SECTION 2

Unique identifiers at unit packet level

Article 6

Marking by means of unit level UIs

1 Manufacturers and importers shall mark each unit packet manufactured or imported in the Union with a unique identifier ('unit level UI') compliant with Article 8.

2 In the case of tobacco products that are manufactured outside the Union, the unit level UI shall be applied on the unit packet before the tobacco product is imported in the Union.

Article 7

Verification of unit level UIs

1 Manufacturers and importers shall ensure that the application of unit level UIs is directly followed by the verification of those unit level UIs in terms of correct application and readability.

2 The process referred to in paragraph 1 shall be protected with an anti-tampering device supplied and installed by an independent third party who shall provide a declaration to the relevant Member States and the Commission that the installed device meets the requirements of this Regulation.

3 Where the process referred to in paragraph 1 fails to confirm the correct application and full readability of the unit level UI, manufacturers and importers shall re-apply the unit level UI.

4 Manufacturers and importers shall ensure that the information recorded by the anti-tampering device remains available for a period of nine months from the time of recording.

5 Manufacturers and importers shall, upon request from Member States, provide full access to the record of the verification process created by the anti-tampering device.

6 By way of derogation from paragraphs 2, 4 and 5, the obligation to install an anti-tampering device shall not apply:

- a until 20 May 2020 to production processes operated by economic operators, or where applicable, the group of undertakings to which they belong, that handled less than 120 million unit level UIs at Union level during the calendar year 2019;
- b until 20 May 2021 to production processes operated by economic operators falling under the definition of small and medium enterprises set out in Commission Recommendation 2003/361/EC⁽¹⁾;
- c to fully manual production processes.

Article 8

Structure of unit level UIs

1 Each unit packet of tobacco products shall be marked with a unit level UI. It shall consist of as short a sequence of alphanumeric characters as possible, not exceeding 50

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characters. The sequence shall be unique to a given unit packet and shall be composed of the following data elements:

- a in the first position, the alphanumeric characters that constitute the ID issuer identification code assigned pursuant to Article 3(4);
- b an alphanumeric sequence, whose probability to be guessed shall be negligible and in any case lower than one in ten thousand ('serial number');
- c a code ('product code') allowing for the determination of the following:
 - i. the place of manufacturing;
 - ii. the manufacturing facility referred to in Article 16;
 - iii. the machine used to manufacture the tobacco products referred to in Article 18;
 - iv. the product description;
 - v. the intended market of retail sale;
 - vi. the intended shipment route;
 - vii. where applicable, the importer into the Union;
- d in the last position, the time stamp in the form of a numeric sequence of eight characters, in the format YYMMDDhh, indicating the date and time of manufacture.

2 ID issuers shall be responsible for the generation of a code consisting of the elements listed in paragraph 1, points (a), (b), and (c).

3 Manufacturers or importers shall add the time stamp referred to in paragraph 1, point (d), to the code generated by the ID issuer pursuant to paragraph 2.

4 Unit level UIs shall not include any data elements other than those listed in paragraph 1.

Where ID issuers use encryption or compression for the generation of unit level UIs, they shall inform the competent authorities of the Member States and the Commission of algorithms used for such encryption and compression. Unit level UIs shall not be reused.

Article 9

Request and issuing of unit level UIs

1 Manufacturers and importers shall send a request to the competent ID issuer for unit level UIs referred to in Article 8. Requests shall be introduced electronically, in accordance with Article 36.

2 Manufacturers and importers introducing such a request shall supply the information listed in point 2.1. of Section 2 of Chapter II of Annex II, in the format indicated therein.

3 The ID issuer shall, within two working days from the receipt of the request and in the order indicated:

- a generate the codes referred to in Article 8(2);
- b transmit the codes along with the information referred to in paragraph 2 of this Article via the router to the primary repository of the requesting manufacturer or importer, as established under Article 26; and

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- c electronically transmit the codes to the requesting manufacturer or importer.

4 However, a Member State may require ID issuers to offer physical delivery of unit level UIs as an alternative to electronic delivery. In cases where physical delivery of unit level UIs is offered, manufacturers and importers shall specify whether physical delivery is requested. In that case, the ID issuer shall within 10 working days from the receipt of the request, and in the following order:

- a generate the codes referred to in Article 8(2);
- b transmit the codes along with the information referred to in paragraph 2 via the router to the primary repository of the requesting manufacturer or importer, as established under Article 26;
- c deliver the codes to the requesting manufacturer or importer in the form of optical barcodes, compliant with Article 21, placed on physical carriers, such as adhesive labels.

5 Within one working day, manufacturers and importers may cancel a request which was sent pursuant to paragraph 1 by means of a recall message as further defined in Point 5 of Section 5 of Chapter II of Annex II.

SECTION 3

Unique identifiers at aggregated packaging level

Article 10

Marking by means of aggregated level UIs

1 Where economic operators choose to comply with the recording obligations provided for under Article 15(5) of Directive 2014/40/EU by means of the recording of aggregated packaging, they shall mark aggregated packages containing tobacco products with a unique identifier ('aggregated level UI').

2 Aggregated level UIs shall be generated and issued on the basis of a request to the competent ID issuer or directly by the economic operator.

3 Where the aggregated level UI is generated on the basis of a request to the competent ID issuer, it shall comply with the structure set out in Article 11(1).

4 Where the aggregated level UI is generated directly by the economic operator, it shall consist of an individual unit code generated in accordance with ISO/IEC 15459-1:2014 or ISO/IEC 15459-4:2014 or their latest equivalents.

Article 11

Structure of aggregated level UIs generated by ID issuers

1 For aggregated level UI generated on the basis of a request to the competent ID issuer, the structure of the aggregated level UI shall consist of a sequence of a maximum of 100 alphanumeric characters that is unique to a given aggregated package and shall be composed of the following data elements:

- a in the first position, the alphanumeric characters that constitute the ID issuer identification code assigned under Article 3(4);

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- b an alphanumeric sequence, whose probability to be guessed shall be negligible and in any case lower than one in ten thousand ('serial number');
 - c the identifier code of the facility (as set out in Article 16) in which the aggregation process took place;
 - d in the last position, the time stamp in the form of a numeric sequence of eight characters, in the format YYMMDDhh, indicating the date and time of aggregation.
- 2 ID issuers shall be responsible for the generation of a code consisting of the elements listed in paragraph 1, points (a), (b), and (c).
- 3 Economic operators shall add the time stamp, referred to in paragraph 1, point (d), to the code generated by the ID issuer pursuant to paragraph 2.
- 4 The aggregated level UI may be completed by the economic operator with additional information, provided that the maximum character limit set out in paragraph 1 is not exceeded. Any such information may only appear after the data referred to in paragraph 1.

Article 12

Link between UI levels

- 1 The aggregated level UI shall be capable of identifying the list of all unique identifiers contained within the aggregated packaging by means of an electronically accessible link to the repositories system.
- [^{X12} In order to establish the link referred to in paragraph 1, manufacturers and importers shall transmit to their primary repository the information listed in point 3.2 of Section 3 of Chapter II of Annex II, in the format indicated therein.]
- 3 In order to establish the link referred to in paragraph 1, economic operators other than manufacturers and importers shall transmit via the router to the secondary repository the information listed in point 3.2 of Section 3 of Chapter II of Annex II, in the format indicated therein.]

Editorial Information

- X1** Substituted by [Corrigendum to Commission Implementing Regulation \(EU\) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products \(Official Journal of the European Union L 96 of 16 April 2018\)](#).

Article 13

Request and issuing of aggregated level UIs generated by ID issuers

- 1 Economic operators requesting aggregated level UIs on the basis of a request to the competent ID issuer shall introduce such requests electronically, in accordance with Article 36.
- 2 Economic operators introducing such requests shall supply the information listed in point 2.2. of Section 2 of Chapter II of Annex II, in the format indicated therein.
- 3 For manufacturers and importers, the ID issuer shall, within two working days from the receipt of the request and in the order indicated:
- a generate the code referred to in Article 11(2);

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- b transmit the codes along with the information referred to in paragraph 2 via the router to the primary repository of the requesting manufacturer or importer, as established under Article 26; and
 - c transmit the codes electronically to the requesting manufacturer or importer.
- 4 For economic operators other than manufacturers and importers, the ID issuer shall, within two working days from the receipt of the request and in the order indicated:
- a generate the code referred to in Article 11(2);
 - [^{X1}b transmit the codes along with the information referred to in paragraph 2 via the router to the secondary repository established under Article 27; and]
 - c transmit the codes electronically to the requesting economic operators.
- 5 Within one working day, economic operators may cancel a request which was sent pursuant to paragraph 1 by means of a recall message as further defined in point 5 of Section 5 of Chapter II of Annex II, in the format indicated therein.
- 6 Aggregated level UIs issued by competent ID issuers shall not be reused.

Editorial Information

- X1** Substituted by [Corrigendum to Commission Implementing Regulation \(EU\) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products \(Official Journal of the European Union L 96 of 16 April 2018\)](#).

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- (1) Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises ([OJ L 124, 20.5.2003, p. 36](#)).

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2020/1496 Sch. 1 para. 47\(c\)](#)
- Art. 2(A1) inserted by [S.I. 2020/1496 Sch. 1 para. 3\(b\)](#)
- Art. 2(1A) inserted by [S.I. 2020/1496 Sch. 1 para. 3\(c\)](#)
- Art. 2(4) words substituted by [S.I. 2020/1496 Sch. 1 para. 3\(d\)](#)
- Art. 2(7) words inserted by [S.I. 2020/1496 Sch. 1 para. 3\(e\)](#)
- Art. 2(8) word substituted by [S.I. 2020/1496 Sch. 1 para. 3\(g\)](#)
- Art. 2(8) words substituted by [S.I. 2020/1496 Sch. 1 para. 3\(f\)](#)
- Art. 2(9) word substituted by [S.I. 2020/1496 Sch. 1 para. 3\(g\)](#)
- Art. 2(13) substituted for Art. 2(13)(14) by [S.I. 2020/1496 Sch. 1 para. 3\(h\)](#)
- Art. 2(15) substituted by [S.I. 2020/1496 Sch. 1 para. 3\(i\)](#)
- Art. 2(16) omitted by [S.I. 2020/1496 Sch. 1 para. 3\(j\)](#)
- Art. 2(17) words substituted by [S.I. 2020/1496 Sch. 1 para. 3\(k\)](#)
- Art. 2(18) substituted by [S.I. 2020/1496 Sch. 1 para. 3\(l\)](#)
- Art. 7(6)(a) omitted by [S.I. 2020/1496 Sch. 1 para. 8\(e\)](#)
- Art. 8(1)(c)(vii) words substituted by [S.I. 2020/1496 Sch. 1 para. 9\(a\)\(ii\)](#)
- Art. 9(3)(b) words substituted by [S.I. 2020/1496 Sch. 1 para. 10\(b\)](#)
- Art. 9(4)(b) words substituted by [S.I. 2020/1496 Sch. 1 para. 10\(b\)](#)
- Art. 9A inserted by [S.I. 2020/1496 Sch. 1 para. 11](#)
- Art. 13(3)(b) words substituted by [S.I. 2020/1496 Sch. 1 para. 17\(b\)](#)
- Art. 13(4)(b) words substituted by [S.I. 2020/1496 Sch. 1 para. 17\(c\)](#)
- Art. 24(1)(a) words omitted by [S.I. 2020/1496 Sch. 1 para. 29\(a\)\(ii\)\(bb\)](#)
- Art. 24(1)(a) words substituted by [S.I. 2020/1496 Sch. 1 para. 29\(a\)\(ii\)\(aa\)](#)
- Art. 24(1)(b) omitted by [S.I. 2020/1496 Sch. 1 para. 29\(a\)\(iii\)](#)
- Art. 24(1)(c) words substituted by [S.I. 2020/1496 Sch. 1 para. 29\(a\)\(iv\)](#)
- Art. 25(1)(a) omitted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(ii\)](#)
- Art. 25(1)(d) words substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(iii\)\(aa\)](#)
- Art. 25(1)(d) words substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(iii\)\(bb\)](#)
- Art. 25(1)(e) words substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(iv\)](#)
- Art. 25(1)(f) word substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(v\)](#)
- Art. 25(1)(g) words substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(iv\)](#)
- Art. 25(1)(h) words substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(iv\)](#)
- Art. 25(1)(j) words substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(vi\)](#)
- Art. 25(1)(k) substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(vii\)](#)
- Art. 25(1)(l) word substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(viii\)\(aa\)](#)
- Art. 25(1)(l) words substituted by [S.I. 2020/1496 Sch. 1 para. 31\(a\)\(viii\)\(bb\)](#)
- Art. 27(2)(c) words substituted by [S.I. 2020/1496 Sch. 1 para. 35\(b\)\(iv\)](#)
- Art. 32(1)(a) words inserted by [S.I. 2020/1496 Sch. 1 para. 42\(a\)\(ii\)](#)
- Art. 32(8) inserted by [S.I. 2020/1496 Sch. 1 para. 42\(f\)](#)
- Art. 33(5) inserted by [S.I. 2020/1496 Sch. 1 para. 43\(d\)](#)
- Art. 34(4)(a) omitted by [S.I. 2020/1496 Sch. 1 para. 44](#)
- Art. 36(1)(b) omitted by [S.I. 2020/1496 Sch. 1 para. 46\(a\)\(i\)](#)
- Art. 36(1)(c) word substituted by [S.I. 2020/1496 Sch. 1 para. 46\(a\)\(ii\)](#)
- Art. 36(1)(c)(i) word inserted by [S.I. 2020/1496 Sch. 1 para. 46\(a\)\(iv\)](#)
- Art. 36(1)(c)(i) word substituted by [S.I. 2020/1496 Sch. 1 para. 46\(a\)\(iii\)](#)
- Art. 36(1)(c)(iii) words omitted by [S.I. 2020/1496 Sch. 1 para. 46\(a\)\(vi\)](#)
- Art. 36(1)(c)(ii) and word omitted by [S.I. 2020/1496 Sch. 1 para. 46\(a\)\(v\)](#)