

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 VII

FINAL PROVISIONS

Article 35

Independence

1 ID issuers, providers of repository services and anti-tampering devices as well as, where applicable, their subcontractors shall be independent and exercise their functions impartially.

2 For the purposes of paragraph 1, the following criteria shall be used to assess independence:

- a independence from the tobacco industry in terms of legal form, organisation and decision making. In particular it shall be assessed whether the undertaking or the group of undertakings is not under the direct or indirect control of the tobacco industry, including a minority shareholding;
- b independence from the tobacco industry in financial terms, which will be presumed if, before assuming their functions the undertaking or the group of undertakings concerned generates less than 10 % of its annual worldwide turnover, excluding VAT and any other indirect taxes, from goods and services supplied to the tobacco sector over the past two calendar years, as may be determined on the basis of the most recent approved accounts. For each subsequent calendar year, the annual worldwide turnover, excluding VAT and any other indirect taxes, from goods and services supplied to the tobacco sector shall not exceed 20 %;
- c absence of conflicts of interests with the tobacco industry of the persons responsible for the management of the undertaking or the group of undertakings, including members of the board of directors or any other form of governing body. In particular, they:
 - (1) shall not have participated in company structures of the tobacco industry for the last five years;
 - (2) shall act independently from any pecuniary or non-pecuniary interest linked to the tobacco industry, including possession of stocks, participation in private pension programmes or interest held by their partners, spouses or direct relatives in the ascending or descending line.

3 Where ID issuers, providers of repository services and providers of anti-tampering devices have recourse to sub-contractors, they shall remain responsible for ensuring compliance by those subcontractors with the independence criteria set out in paragraph 2.

4 For the purposes of complying with their obligations under Article 3(8)(a) Member States, as well as the Commission may require ID issuers, providers of repository services and providers of anti-tampering devices, including where applicable their sub-contractors to provide them with documents necessary to assess compliance with the criteria set out in paragraph 2. Such documents may include annual declarations of conformity with the independence

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criteria set out in paragraph 2. Member States and the Commission may require that the annual declarations include a full list of services provided to the tobacco industry during the last calendar year as well as individual declarations of financial independence from the tobacco industry provided by all management members of the independent provider.

5 Any change in circumstances related to the criteria referred to in paragraph 2, capable of affecting the independence of ID issuers, providers of repository services and providers of anti-tampering devices (including, where applicable, their subcontractors), that subsist for two consecutive calendar years, shall be communicated without delay to the relevant Member States and to the Commission.

6 Where, information obtained in accordance with paragraph 4, or the communication referred to in paragraph 5, discloses that providers of repository services and providers of anti-tampering devices (including, where applicable, their subcontractors), no longer meet the requirements laid down in paragraph 2, then within a reasonable time period and at the latest by the end of the calendar year following the calendar year in which the information or communication was received, Member States and, in relation to the provider of secondary repository, the Commission shall take all measures to ensure compliance with the criteria set out in paragraph 2.

7 ID issuers, providers of repository services and providers of anti-tampering devices shall inform without delay the relevant Member States and the Commission about any occurrences of threats or other attempts at exercising undue influence that may actually or potentially undermine their independence.

8 Public authorities or undertakings governed by public law along with their subcontractors shall be presumed independent from the tobacco industry.

9 The procedures governing the appointment of ID issuers, providers of repository services and providers of anti-tampering devices and the monitoring of their compliance with the independence criteria set out in paragraph 2 shall be subject to periodic review by the Commission with a view to assessing their conformity with the requirements of Article 15 of Directive 2014/40/EU and this Regulation. Conclusions of the review shall be published and form part of the report on the application of Directive 2014/40/EU provided for under Article 28 of that Directive.

Article 36

Security and interoperability of communications and data

1 All electronic communication provided for under this Regulation shall be carried out using secure means. Applicable security protocols and connectivity rules shall be based on non-proprietary open standards. They shall be established by:

- a the ID issuer for communications between the ID issuer and the economic operators registering with the ID issuer or requesting unique identifiers;
- b the providers of the primary repositories for communications between the primary repositories and manufactures or importers;
- c the provider of the secondary repository for communications between the secondary repository and the router and:
 - i. the ID issuers;
 - ii. the primary repositories; and

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iii. economic operators using the router, i.e. economic operators other than manufacturers and importers.

2 Providers of primary and secondary repositories shall be responsible for the security and integrity of hosted data. Data portability shall be secured in accordance with the common data dictionary set out in Article 28.

3 For all transfers of data, the sending party is responsible for the completeness of transferred data. In order for the sending party to discharge this obligation, the receiving party shall acknowledge the receipt of transferred data including a checksum value of actual transmitted data or any alternative mechanism allowing for validating the integrity of transmission, in particular its completeness.

Article 37

Transitional provision

1 Cigarettes and roll-your-own tobacco that were manufactured in the Union or imported into the Union before 20 May 2019 and not marked by means of unit level UIs in accordance with Article 6 may remain in free circulation until 20 May 2020. In relation to these tobacco products which are allowed to remain in free circulation, but not marked with a unit level UIs, the obligations referred to in Chapter VI shall not apply.

2 Tobacco products other than cigarettes and roll-your-own tobacco that were manufactured in the Union or imported into the Union before 20 May 2024 and not marked by means of unit level UIs in accordance with Article 6 may remain in free circulation until 20 May 2026. In relation to these tobacco products which are allowed to remain in free circulation, but not marked with a unit level UIs, the obligations referred to in Chapter VI shall not apply.

Article 38

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Changes to legislation:

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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\(a\)\(v\)](#)